Waste Isolation Pilot Plant

SAFETY SOFTWARE QUALITY ASSURANCE ASSESSMENT REPORT

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WIPP SAFETY SOFTWARE QUALITY ASSURANCE ASSESSMENT REPORT

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Acronyms

ASME – American Society of Mechanical Engineers

CASE – Computer-Aided Software Engineering

CFR – Code of Federal Regulations

CH – Contact-Handled

COTS – Commercial off-the-shelf

CRAD – Criteria Review and Approach Document

DOE – Department of Energy

DOELAP – Department of Energy Laboratory Accreditation Program

DOS – Disk Operating System

DSA – Documented Safety Analysis

EPA – Environmental Protection Agency

LANL – Los Alamos National Laboratory

MCNP - Monte Carlo N-Particle

NQA – Nuclear Quality Assurance

NRC – Nuclear Regulatory Commission

PL/SQL – Procedure Language/Structured Query Language

QA – Quality Assurance

QAPD – Quality Assurance Program Document

SCM – Software Configuration Management

SDD – Software Design Description

SOW – Statement of Work

SQA – Software Quality Assurance

SRD – Software Requirements Description

SSCs – Systems, Structures, and Components

SUD – Software User Documentation

TARP – Technology Action Request Process

TLD – Thermoluminescent Dosimeter

V&V –Verification and Validation

WHC – Westinghouse Hanford Company

WIPP – Waste Isolation Pilot Plant

WTS – Washington TRU Solutions

WWIS – WIPP Waste Information System

WP – WIPP Procedure

I. Introduction

This report summarizes the results of a structured assessment to evaluate the adequacy of software quality assurance (SQA) for the systems, structures, and components (SSCs) at the Waste Isolation Pilot Plant (WIPP), a Hazard Category 2 non-reactor nuclear facility. This assessment, conducted in July 2004 by a multidisciplinary team according to the *WIPP SQA Assessment Plan*, is performed to fulfill a commitment in the *Department of Energy Implementation Plan for Defense Nuclear Facilities Safety Board Recommendation 2002-1, Quality Assurance for Safety Software at Department of Energy Defense Nuclear Facilities.*

Safety software, as described in the DOE Implementation Plan, includes both **safety system software** and **safety analysis and design software**. Safety system software includes computer software (human-machine interface software, network interface software, programmable logic controller (PLC) programming language software, safety management database) and firmware that perform safety system functions as part of a Safety Class or a Safety Significant SSC. Safety analysis and design software is software that is not part of an SSC but is used in safety classification, design, and analysis to ensure the proper:

- Accident analysis of nuclear facilities,
- Analysis and design of safety SSCs, and
- Identification, maintenance, and operation of safety SSCs

The only safety SSC at WIPP is the waste hoist brake system, which has been functionally classified as a Safety Significant system. The brake does not use software to perform safety system functions. Therefore, SQA assessment of safety system software is not needed.

Based on an evaluation of the functions supported by various safety analysis and design software, the following four software systems are selected for this assessment:

- WIPP Waste Information System (WWIS)
- Personnel dosimetry software
- Monte Carlo N-Particle (MCNP) code
- GXQ code

WWIS

WWIS is a database used to gather, store, and process information pertaining to transuranic (TRU) waste designated by the DOE for disposal at WIPP. More than 200 users access WWIS on a regular basis to obtain information.

WWIS is a client/server application. The client application runs on personal computers using Microsoft Windows, and the database runs on a UNIX server. The client software is served by an application server to facilitate the dissemination and configuration control of client software. The WWIS application was developed using Oracle Procedure

Language/Structured Query Language (PL/SQL), Oracle Designer/2000, and Developer 2000 tool sets, which use Computer-Aided Software Engineering (CASE) methodology in design and implementation of the application.

Personnel Dosimetry Software

The dosimetry software, Harshaw Dose Calculation Algorithm (HDCA), is proprietary commercial off-the-shelf (COTS) software developed and sold by the Bicron NE Technology Company (now Thermo-Electron). The software takes the output from the Harshaw 8800 Thermoluminescent Dosimeter (TLD) reader and uses the data to calculate a dose. The HDCA software is used at WIPP to calculate doses from personnel dosimeters.

Validation and verification (V&V) of HDCA software by the WIPP Dosimetry Group has been performed using a "black box" approach in which dosimeters exposed to a known amount of radiation were processed and the doses calculated by the software were compared to the known doses. Initial V&V was performed as a part of acceptance testing of the software. Routine validation checks have been performed quarterly since 1989 using the Dosimetry Quality Assurance (QA) blind test protocol, in accordance with DOE Laboratory Accreditation Program (DOELAP) requirements. The WIPP dosimetry laboratory has been accredited by the DOELAP since 1989. This accreditation requires the external dosimetry software to perform as designed. DOELAP accreditation is required by Section 835.402(b) of 10 CFR 835, *Occupational Radiation Protection.* DOE/EH-0026, *Handbook for the Department of Energy Laboratory Accreditation Program for Personnel Dosimetry Systems* and DOE/EH-0027, *Department of Energy Standard for the Performance Testing of Personnel Dosimetry Systems* provide detailed requirements for DOELAP accreditation.

MCNP

MCNP is a COTS/government sponsored application, which is used for criticality and shielding calculations. MCNP was developed by Los Alamos National Laboratory (LANL) and is commercially available both within and outside of the DOE complex. It has about 3,000 users around the world.

MCNP4C2 is the version used at WIPP. The current criticality analysis in the WIPP Contact-Handled Waste Documented Safety Analysis and the shielding analysis for the draft Remote-Handled Waste Documented Safety Analysis are based on MCNP4C2.

GXQ

GXQ, Version 4.0A, is a Hanford-developed software program, which operates on a DOS-based system, providing a mathematical function for calculating atmospheric dispersion coefficients (X/Q). This program was acquired from the Westinghouse Hanford Company (WHC), for use at WIPP by the WIPP Nuclear Safety Analysis group. As noted in WP 02-RP.01, Revision 0, *WIPP Site Atmospheric Dispersion Coefficient (X/Q) Calculations,* GXQ has been verified to produce X/Q values consistent with NRC RG 1.145, *Atmospheric*

Dispersion Models for Potential Accident Consequence Assessments at Nuclear Power Plants, methodology (Faulk, 2000).

The first use of GXQ 4.0A for safety analysis calculations was documented in Revision 5 of the WIPP Contact-Handled (CH) Waste Documented Safety Analysis, DOE/WIPP-95-2065, dated June 2001. GXQ 4.0A-produced X/Q values have been used in each subsequent revision. Revision 0 through Revision 4 of the CH DSA used calculations specified in NUREG 1.145 Guide to determine X/Q values. GXQ 3.1 was not used for safety analysis calculations, but was used to evaluate the different stack and ground level releases and how they affected the dispersion coefficients.

This assessment focused on the performance of the software in WIPP applications, from the user's perspective. The report of a recent assessment performed by the Richland Office (RL), which addressed all QA aspects of the GXQ software, was reviewed and referenced. The WIPP assessment intentionally avoided redundancy with the RL assessment, especially in the area of software development.

Assessment Team

The DOE Carlsbad Field Office (CBFO) Authorization Basis Senior Technical Advisor (ABSTA), Chuan-Fu Wu, was appointed Team Leader for the WIPP SQA Assessment Team. The ABSTA is well-experienced in assessment techniques and leadership skills. His qualifications and experience related to QA assessment include the following:

- DOELAP Assessor and Oversight Board member
- Health Physics Society Laboratory Accreditation Assessment Committee (LAAC) Chairman
- Facility Readiness Assessment Team Leader
- Qualified Lead Auditor.

Appendix A provides a brief biographical sketch documenting the technical and leadership capabilities of the Assessment Team Leader.

In consultation with the CBFO Acting Manager and Deputy Manager, the Assessment Team Leader selected three team members from the CBFO, one from the CBFO Technical Assistance Contractor (CTAC), and three from the WIPP management & operating (M&O) contractor, Washington TRU Solutions (WTS):

- Lea Chism, CBFO QA Specialist
- Richard Farrell, CBFO Safety Officer
- Bill Keeley, WTS Chief Information Officer
- Reinhard Knerr, CBFO TRU Waste Certification Work Coordinator
  (Note: Mr. Knerr took a job with another DOE office and left CBFO in August 2004)
- Cathy Nesser, WTS QA Analyst
- Andy Stanley, CTAC Safety and Regulatory Compliance Specialist

- Dave Wiedenhoeft, WTS QA Specialist

All team members have demonstrated capability in performing technical assessment of safety analysis and design software. As a group, the Assessment Team has working knowledge of hazard and safety analysis, safety classification of SSCs, software development practices, system engineering, software applications, and QA practices. Biographical sketches of the team members are provided in Appendix A.

II. Assessment Methodology, Criteria, Lines of Inquiry, and Tailoring

This assessment follows the criteria and guidelines of the DOE SQA Criteria Review and Approach Document (Appendix B, developed from CRAD – 4.2.4.1, Revision 3, October 24, 2003), *Assessment Criteria and Guidelines for Determining the Adequacy of Software Used in the Safety Analysis and Design of Defense Nuclear Facilities.*

The CRAD identifies eight topical areas covering a typical software life cycle:

- Software Requirements Description (SRD)
- Software Design Description (SDD)
- Software User Documentation (SUD)
- Software Verification and Validation (V&V)
- Software Configuration Management (SCM)
- Software Quality Assurance
- Software Procurements
- Software Problem Reporting and Corrective Action

Each of the four software systems is assessed for all the topical areas to the extent applicable. A sub-team was assigned to assess each system, as shown in the following matrix:

Safety Software	Lead Member	Support Member
WWIS	Reinhard Knerr	Bill Keeley and Lea Chism
Personnel Dosimetry	Richard Farrell	Andy Stanley
MCNP	Dave Wiedenhoeft	Cathy Nesser
GXQ	Cathy Nesser	Dave Wiedenhoeft

The Assessment Team Leader was responsible for leading and integrating all assessment activities and was not assigned to any specific sub-team. The sub-teams used document reviews, personnel interviews, and field visits as the primary means of gathering information and assessing the SQA. A set of generic lines of inquiry, tailored as necessary, was used as a check-list to record assessment results (Appendices C, D, E, and F).

WWIS

Only four of the 40 criteria were not fully applicable to the WWIS software (see 4.2.2, 4.4.4, 4.5.6, and 4.8.6 of Appendix C). Most of these criteria were N/A, because they concerned safety components that are not applicable to WWIS.

Personnel Dosimetry Software

For the HDCA, the criteria and approach were tailored for application to this specific software package. Tailoring was accomplished in two ways. First, it was noted that some of the topical areas to be assessed did not fully apply to this software. For example, the HDCA software contains no safety components, so references to assessment of safety components were removed from the criteria and approach under SDD. In addition, the criteria under SUD were tailored to remove considerations regarding databases, since HDCA software does not utilize databases for calculating dose from the TLD reader output. In the end, two of the criteria in the tailored checklist were N/A (see 4.5.6 and 4.8.3 in Appendix D).

The second type of tailoring employed in assessment of the HDCA software focused on the methodology used to assess the vendor's QA practices relating to software design, development, configuration management, and V&V. As explained earlier, HDCA is COTS software that is developed, maintained, controlled, and modified solely by the vendor. It is procured and implemented by the user through a license by the vendor, under which no modifications are allowed. The scope of this assessment did not include assessment of the vendor or its facilities and operations. However, the vendor is on the WIPP Qualified Supplier List. In accordance with its own QA requirements, WIPP conducts annual QA reviews of all qualified suppliers.

In addition, WIPP performs a thorough audit of the vendor prior to accepting a new version of the software to ensure adequate quality assurance is implemented. WIPP QA Audit E98-06A was performed for the current software version. The scope of this audit included the QA aspects of software development, maintenance, control, and modification. Therefore, the results of the audit were used to indirectly verify those criteria that applied but were not capable of being directly verified by assessing vendor operations.

A combination of indirect verification through results of WIPP QA audits of the vendor and an a posteriori approach including verification of initial acceptance testing and routine quarterly re-validation in accordance with DOELAP requirements at WIPP was used to assess software V&V. This strategy provided assurance that appropriate QA processes were applied during software testing by the vendor, but even more importantly, proved that the software as used at WIPP provided results that satisfied WIPP requirements.

MCNP and GXQ

Some of the topical areas do not fully apply to the MCNP and the GXQ software systems, such as software requirements description, software design documentation, and configuration management, since these activities are performed by the developer during the development phases and were not directly verified. The developer of either software, a DOE facility, is required to implement applicable QA requirements for the development phases, configuration control, program maintenance and updating, and other activities performed by the developer. The GXQ software was assessed by Hanford for the DOE safety software QA assessment. The Hanford assessment report was reviewed by the WIPP assessment team. Only one criterion in the tailored MCNP checklist is N/A (see 4.7.1 in Appendix E) and two in the tailored GXQ checklist are N/A (see 4.5.6 and 4.7.1 in Appendix F).

The WIPP assessment focused on SQA activities that could be verified at the user site. For example, assessment of V&V focused on activities performed by the user to verify and validate the software package for use within the user's operations. Assessment of the procurement element considered the user's SQA program requirements for acquisition of COTS/government sponsored software. In addition to assessment of the user's SQA activities, the developer-supplied documentation was reviewed and the information supplied for each element was considered.

III. Assessment Results

At WIPP, the governing standard for SQA is ASME NQA-2a-1990 addenda, Part 2.7, which is imposed by EPA regulation 40 CFR 194.22, "Quality Assurance," and implemented by DOE/CBFO-94-1012, *Quality Assurance Program Document (QAPD)*, WP 13-1, *WTS Quality Assurance Program Description,* and WP 16-2, *Software Screening and Action Plan.* These requirements are effectively implemented for the software systems assessed.

WWIS

For the WWIS software, the CRAD – 4.2.4.1 criteria and guidelines were satisfied with two non-critical exceptions. The two areas needing improvement are the following:

- The WWIS SDD needs updating (see 4.2.4 in Appendix C)
- Specific WWIS installation instructions need to be included in software configuration management documentation (see 4.5.4 in Appendix C)

The WWIS team agreed with these recommendations and developed action plans to address them. It is important to note that these two improvement actions are enhancements that do not affect database information or safety. Therefore, the assessors concluded that the WWIS software is performing its intended functions in its current condition.

The WWIS team operates the WWIS system in compliance with its software documents, user's manual, applicable WIPP quality assurance procedures, and industry standards.

Personnel Dosimetry Software

The dosimetry software and its implementation at WIPP satisfy the assessment criteria and the results of the assessment indicate that the software is capable of performing its intended function and meeting WIPP user requirements. In conducting this assessment, all topical areas were considered, within the tailoring constraints discussed above. No findings or observations resulted from the assessment of this software.

MCNP and GXQ

The assessment criteria were generally satisfied for the MCNP and the GXQ software systems, and indicate that each software application is capable to perform its intended function and meet the user's requirements. All of the topical areas were considered for this assessment, to the extent applicable to COTS/government sponsored software. Some areas, such as requirements description and design documentation were not fully applicable, but supporting information received from the developers was reviewed and found acceptable. The user performed installation testing to validate the program for use.

IV. Lessons Learned

SQA Checklist

The use of a standardized, detailed assessment checklist built directly from the CRAD – 4.2.4.1 criteria and guidelines (see Appendices C, D, E, and F) was very helpful in ensuring consistency and completeness among the various software assessments.

Restriction of COTS assessments to implementation and use at WIPP

This assessment attempted to indirectly verify some aspects of software development, maintenance, control, and V&V in whole or in part through review of audit reports resulting from WIPP QA audits of the vendor. Although this provided reasonable assurance that the criteria in question were being met by the vendor, if questions arose regarding the specifics of the audit, it was often difficult to obtain answers due to the unavailability of individuals that had performed the audit. Future SQA assessments of COTS at WIPP should be restricted to those topical areas that can be directly assessed through observations of WIPP practices, review of WIPP-specific documentation, and interview of WIPP users.

V. Detailed Results

This section, along with the checklist found in Appendices C, D, E, and F) provides detailed results for each of the four software application.

WWIS

WWIS Software Requirements Description (SRD)

All SRD criteria were met (see 4.1 of Appendix C for details). There were no quality-related SRD issues or concerns. There were no SRD areas needing improvement. There were no recommended changes to criteria and guidance related to SRD.

WWIS Software Design Description (SDD)

All applicable SDD criteria were met except one (see 4.2 in Appendix C for details). The one SDD issue/improvement was that the SDD needs updating. The WWIS team developed a corrective action plan to update the SDD by 07/05. Work on updating the WWIS will begin following the release of 5.0, because significant changes are anticipated. There were no recommended changes to criteria and guidance related to SDD.

WWIS Software User Documentation (SUD)

All SUD criteria were met (see 4.3 in Appendix C for details). There were no quality-related SUD issues or concerns. There were no SUD areas needing improvement.
There were no recommended changes to criteria and guidance related to SUD.

WWIS Software Verification and Validation (V&V)

All applicable V&V criteria were met (see 4.4 in Appendix C for details). There were no quality-related V&V issues or concerns. There were no V&V areas needing improvement. There were no recommended changes to criteria and guidance related to V&V.

WWIS Software Configuration Management (SCM)

All applicable SCM criteria were met except one (see 4.5 in Appendix C for details). The one SDD issue/improvement was that the SCM documentation needs to include specific WWIS installation instructions. The WWIS team developed a corrective action plan to include specific installation instructions in the SCM by 01/05. There were no recommended changes to criteria and guidance related to SCM.

WWIS Software Quality Assurance (SQA)

All SQA criteria were met (see 4.6 in Appendix C for details). There were no quality-related SQA issues or concerns. There were no SQA areas needing improvement. There were no recommended changes to criteria and guidance related to SQA.

WWIS Software Procurements

All applicable software procurement criteria were met (see 4.7 of Appendix C for details). There were no quality-related software procurement issues or concerns.
There were no software procurement areas needing improvement. There were no recommended changes to criteria and guidance related to software procurement.

WWI Software Problem Reporting and Corrective Action

All applicable problem reporting/corrective action criteria were met (see 4.8 of Appendix C for details). There were no quality-related problem reporting/corrective action issues or concerns. There were no problem reporting/corrective action areas needing improvement. There were no recommended changes to criteria and guidance related to problem reporting/corrective action.

Personnel Dosimetry Software

Dosimetry Software Requirements Description (SRD)

Specific SRD documentation was not available for review. However, the vendor's user manual was reviewed. Sections 9 and 10 of the manual list the functional and performance requirements for dosimetry software. Configuration control and documentation maintenance were verified indirectly through WIPP QA audits of the vendor. The applicable requirements and guidelines are specified in the DOELAP Handbook (DOE/EH-0026) and the DOELAP Standard (DOE/EH-0027). Implementation of the requirements at the WIPP Dosimetry Laboratory has provided a posteriori verification that the software was properly designed and developed. Criteria for this topical area were thus verified as having been met.

Dosimetry Software Design Description (SDD)

Criteria associated with this topical area were verified through a combination of documentation review and interviews with the primary software user. As with the SRD, no stand-alone SDD documentation was available for review. Sections 7-10 of the user's manual contain sufficient design information to enable the software to be properly implemented at WIPP and to support WIPP user needs. Configuration and change control processes were verified indirectly through WIPP QA audits of the vendor. The WIPP purchase requisition process provides the appropriate controls to ensure that the design is reviewed and updated as necessary and that any modifications to the software by the vendor are properly evaluated at WIPP prior to implementation. Criteria for this topical area were verified to have been met.

Dosimetry Software User Documentation (SUD)

The criteria for this topical area were met. User documentation for this software was adequate for implementation and use of the software at WIPP. Interviews with the primary user of the software indicated no problems to date with the performance of the software and that troubleshooting assistance is readily available from the vendor when needed. Although no training requirements were listed in the user documentation, they were unnecessary, since training on software use is required at WIPP and initial and recurrent training is adequately implemented. WIPP requires completion of Qualification Cards D01, *Harshaw 8800C TLD System Equipment Qualification* Card, and DS02, *Processing Center Qualification* Card, prior to being allowed to run the software. Criteria for this area were tailored to remove references to "database maintenance" since this software does not use databases for calculating dose from the TLD reader output.

Dosimetry Software Verification and Validation (V&V)

Software V&V by the vendor was assessed indirectly through the results of WIPP vendor audits and found to be acceptable. In addition, initial validation of the software for use at WIPP was performed as a part of acceptance testing. Routine quarterly re-validation and re-validation upon implementation of vendor modifications are performed to ensure that the software continues to perform as expected and with the required accuracy.

WIPP initial and re-validation efforts are performed using a test plan that is prepared in accordance with the DOELAP requirements instituted by the WIPP Dosimetry Laboratory, as presented in the DOELAP Standard (DOE/EH-0027). The standard defines a set of reference performance tests to help establish a uniform approach to personnel dosimetry. The purpose of the standard is to describe minimum levels of acceptable performance and to provide procedures for the performance testing of personnel dosimetry systems.

As required by Sections 2 and 3 of the standard, the WIPP Dosimetry Blind Test Protocol incorporates the use of TLDs exposed to known radiation doses against which to compare the doses calculated by the software.

The criteria associated with this topical area are verified to have been met.

Dosimetry Software Configuration Management (SCM)

Since this is COTS software, the vendor is responsible for software configuration management. Most criteria associated with this topical area were thus verified indirectly through WIPP QA audits of the vendor. However, WIPP maintains a current copy of the vendor's revision history for the software. WIPP procedures (WP 12-3 and WP 12-OS132) require satisfactory demonstration of the ability of any modifications made to the software by the vendor to meet DOELAP performance requirements before any such modifications are implemented at WIPP. Interviews with the WIPP Dosimetry Team Leader confirmed that WIPP line, engineering, and QA managers understand the importance of properly implementing software change control at WIPP.

There has only been one modification by the vendor to this software since it has been used at WIPP. The software was first developed in 1989. It was modified in July 1998 and changes to the SDD were reviewed by WIPP as a part of Audit No. E98-06A at the vendor site to verify that this modification was made under appropriate QA controls. Acceptance testing was then conducted at WIPP to ensure that the modified software performed properly and in accordance with DOELAP specifications when implemented.

Criteria associated with this topical area were verified to have been met.

Dosimetry Software Quality Assurance (SQA)

WIPP Procedure WP 12-3 places responsibility for software quality control for COTS software on the vendor. Proper vendor SQA for this software was verified through WIPP vendor audits. However, WIPP has a documented SQA Plan (WP 16-IT3117) that identifies the applicable software product, the responsible WIPP organization, and the required documentation that must be maintained for implementation and use of the software. In addition, WIPP uses the Software and Documentation Feedback form provided in the user's manual as a part of its SQA documentation.

The criteria for this topical area were verified to have been met.

Dosimetry Software Procurements

As explained in the results for previous topical areas, vendors that supply COTS (as well as other software) are evaluated initially and on a recurrent basis by WIPP to ensure that they develop software under an appropriate QA program and are capable of providing software that satisfies the specific requirements for which it was purchased. Vendors that meet and maintain these requirements are placed on the WIPP Qualified Supplier List. The HDCA software was purchased from such a vendor.

The criteria for this topical area were verified to have been met.

Dosimetry Software Problem Reporting and Corrective Action

Interviews with the WIPP Dosimetry Team Leader and review of associated documentation revealed that WIPP has a well-documented process for reporting and correcting problems associated with the HDCA software. The WIPP Technology Action Request Process (TARP) is the formal feedback process used by WIPP for this purpose. The troubleshooting form provided by the vendor in the user's manual is integrated into this process to ensure efficient reporting of software problems. The vendor also provides technical assistance in resolving software problems through its customer service support network.

The criteria for this topical area were verified to have been met.

MCNP

MCNP Software Requirements Description (SRD)

This element is partially applicable to this government agency sponsored software, and the criteria were met to the extent they are applicable. The MCNP user manual was reviewed and the primary user was interviewed for the assessment of this element.

A detailed SRD for the development phase was not supplied with the software. Development, review and update, configuration management, and document control are performed by the developer and were not verified by this assessment. However, the MCNP user manual supplied with the software includes a functional description of the requirements implemented by the software, which are satisfactory and appropriate for the user's needs.

MCNP Software Design Description (SDD)

This element is partially applicable to this government agency sponsored software, and the criteria were met to the extent they are applicable. The MCNP user manual was reviewed, and the primary user was interviewed for the assessment of this element.

A detailed SDD was not supplied with this government agency sponsored software. Development, review and update, configuration management, and document control are performed by the developer and were not verified by this assessment. However, the MCNP user manual supplied with the software addresses the criteria for this element, including a functional description of the design implemented by the software, which is satisfactory and appropriate for the user's needs.

MCNP Software User Documentation (SUD)

The criteria for this element were met. The MCNP user manual and related web site were reviewed, and the primary user was interviewed for the assessment of this element. Extensive user documentation was provided with the software, including discussion of the software requirements, design, system requirements and limitations, installation procedures, input and output specifications, error messaging, and test problems for user validation. The developer also maintains a web site dedicated to this software, with additional information.

MCNP Software Verification and Validation (V&V)

The criteria were met as they were applied to this software. The MCNP user manual and user V&V documentation were reviewed, and the primary user and responsible manager were interviewed for the assessment of this element. The user performed and documented testing to validate that the software performed correctly on the user's system and documented the system configurations on which tests were run. V&V of the development phases were not verified by this assessment. However, the MCNP user manual included a V&V Plan, which addressed the requirements of this section, and the developer certified in the MCNP user

manual that the software was verified and validated in accordance with the V&V Plan.

MCNP Software Configuration Management (SCM)

The criteria were met as applicable to this software. The MCNP user manual and user SQA documentation were reviewed, and the primary user and responsible manager were interviewed for the assessment of this element. The software components are identified in the MCNP Manual and in the user's documentation. The user's procedure, WP 16-2, governs management of modifications and installation of new versions. This software has not been modified by the user, but the user has followed the procedure requirements for installation and management of modifications and new versions received from the developers.

The MCNP Manual contains a SCM Plan, which addresses the requirements of this section. The MCNP developers are responsible for configuration management of the program. The user's documentation (SQA Checklist, user V&V documentation) addresses configuration management of the version and components under the user's control. Applicable items, such as the MCNP user manual and user V&V documentation, are maintained by the user in accordance with WP 16-2.

MCNP Software Quality Assurance (SQA)

The criteria were met. The MCNP user manual and user V&V documentation were reviewed for this element. The user documented a SQA Plan (WP 16-IT3117, Attachment 1), which identified the applicable software product, responsible organization, and required documentation. WP 16-2 provides general requirements for error reporting. The user effectively implemented the SQA controls in accordance with the Plan and WP 16-2.

The MCNP Manual contains a SQA Plan, which addresses the requirements of this section. The MCNP developers are responsible for application of SQA controls during the development phases.

MCNP Software Procurements

The criteria were generally met as applicable to this software. The user SQA Plan and V&V documentation were reviewed, and the primary user and responsible manager were interviewed for the assessment of this element. SQA requirements for acquired software are established in WP 16-2, which implements the requirements of ASME NQA-2a-1990 addenda, Part 2.7. For software not developed for WIPP, i.e., COTS or government sponsored software, both WP 16-2 and NQA-2a-1990 Part 2.7 require that the user perform an evaluation to determine the adequacy of the software and its ability to meet the user's requirements; neither requires an evaluation of the vendor's QA program.

MCNP is government-sponsored software, obtained from another DOE site (LANL). The user SQA Plan identified SQA requirements applicable to this software, in accordance with

WP 16-2. User V&V, including testing, verified that the specified SQA requirements were accomplished and the software was acceptable for use.

MCNP Software Problem Reporting and Corrective Action

The criteria were met. The MCNP user manual and the user's SQA and corrective action procedures were reviewed, and the primary user was interviewed for the assessment of this element. WP 16-2 and WP 04-IM1000 provide for reporting, tracking, and resolving problems affecting the site, and include requirements to report defects to the software supplier. The MCNP Manual provides contact information and instructions for reporting defects to the developer. The MCNP Manual also refers to the LANL/MCNP web site, which has provisions for reporting and disseminating problem information online.

Corrective actions, notifications to all users, and the software change process are the responsibility of the developers. The MCNP Manual discusses the developers' corrective action, reporting, and change control processes.

GXQ

GXQ Software Requirements Description

Use of GXQ at WIPP has been limited to the unmodified Version 4.0A (E-mail from Hey to Nesser, July 2004). Supporting documentation on file and reviewed during the assessment includes [Westinghouse Hanford Company] WHC-SD-GN-SWD-30002, Revision 0, *GXQ 3.1 Users' Guide* [which includes code verification] (Hey, 1993); WHC-SD-GN-SWD-30002, Revision 1A, *GXQ 4.0 Program Users' Guide* (Hey, 1994); and, WHC-SD-GN-SWD-30003, Revision 1, *GXQ Program Verification and Validation* (Hey, 1995).

Because GXQ 4.0A is the program version currently in use, this assessment focused on documentation primarily pertaining to Version 4.0A. The GXQ 4.0 Program Users' Guide includes Sections relative to software use, process flow diagrams, configuration control, hardware and software requirements, execution, methodology, input description (interactions), and error and warning messages, and example usage.

WHC-SD-GN-SWD-30003, Revision 1, *GXQ Program Verification and Validation* (V&V) document was distributed under WHC Information Release Administration, and reviewed according to procedure WHC-CM-3-4.

GXQ Software Design Description

Software Design Description text is included in WHC-SD-SWD-3003, Revision 1, *GXQ Program Verification and Validation* (Hey, 1995), and WHC-SD-GN-SWD-30002, Revision 1A, *GXQ 4.0 Users' Guide*. Within WHC-SD-GN-SWD-3002, are a technical description of the program, appropriate inputs, flow diagrams of subroutines, and discussion of errors and warnings (Hey, 1994).

The sequential document numbering of these documents indicates that they are included in a WHC document control program. Within WHC-SD-GN-SWD-30003, Revision 1, *GXQ Program Verification and Validation*, it is stated that the testing requirements of WHC-CM-6-32, *Safety Analysis and Regulation Work Procedures*, Section 4.3, Revision 0, *Software Configuration Control*, are fulfilled. Also included as a reference document is WHC-CM-4-2, *WHC Quality Assurance Manual*, QI 3.2, Revision 2, *Software Quality Assurance Requirement* (Hey, 1995). This V&V document was provided to WIPP under the cover of a signed Release Authorization, and following a Hanford procedure, WHC-CM-3-4, providing further indication of control processes.

Per the program developer, although some specialized modifications have been produced and qualified at the Hanford facility, they were not available for general distribution (E-mail from Hey to Nesser, July 2004). The latest version of GXQ used at the WIPP is 4.0A. Included in the V&V document is a record of revision (last entry May 1995). WIPP file documents refer to GXQ 4.0 and 4.0A. Per the program developer, Version 4.0A contained a small technical change from 4.0, which affected the way the source depletion model was used in combination with the virtual source model. The use of these models in combination would be rare and the effect small for most receptor locations. The Users' Guide and V&V documentation, however, were not impacted (E-mail from Hey to Nesser, July 2004).

GXQ Software User Documentation

Users' Guide, WHC-SD-GN-SWD-30002, Revision 1A offers various corrective actions for error messages. There are, however, neither recommendations for routine database maintenance nor instructions for performing this maintenance. A statement is made that maintenance is the responsibility of the user (Hey, 1994).

From the user's perspective, there is no database in the GXQ program. WIPP procedure WP 16-2, §5.2.6, *Operations and Maintenance Phase*, however, charges the WIPP software custodian with the responsibility to maintain and correct the software, as necessary. Further, WP 16-2, requires that software modifications be approved, documented, verified and validated, controlled, and in-use tests performed. Per the cognizant engineer, during WIPP use of GXQ, there have been no errors, problems, or failures attributable to the GXQ program (E-mail from Hey to Nesser, July 2004).

GXQ Software Verification and Validation

Current and historical V&V documentation is on file at WIPP. The Users' Guides for both Versions 3.1 and 4.0A were made available to the auditor during this assessment.
The V&V documentation for Version 3.1 is embedded within WHC-SD-GN-SWD-30002, Revision 0, *GXQ 3.1 Users' Guide* (Hey, 1993), V&V documentation (WHC-SD-GN-SED-30003, Revision 1), and the Users' Guide (WHC-SD-GN-SWD-30002, Revision 1A) for GXQ 4.0 are separate, stand-alone documents (Hey, 1995).

Included in WHC-SD-GN-SED-30003, Revision 1, *GXQ Program Verification and Validation,* are a list of code libraries used; reference to ANSI/ANS-10.4-1987, *Guides for Verification and Validation of Scientific and Engineering Computer Programs for the Nuclear Industry*; and, NRC-RG 1.145, Revision 1, *Atmospheric Dispersion Models for Potential Accident Consequence Assessments at Nuclear Power Plants* (Hey, 1995).

Codes and formulae on which GXQ functions are based are identified in WHC-SD-GN-SWD-30002, Revision 1A, *GXQ 4.0 Program Users' Guide*, Section 3.0, *Execution* (Hey, 1995).

GXQ Software Configuration Management

Although Software Configuration Management is addressed in WHC-SD-GN-SWD-30002, Revision 1A, *GXQ Program Users' Guide*, limited documentation of software configuration control for GXQ at the developing site was available during the audit (Hey, 1995). Two instances of revision were, however, documented in WHC-SD-GN-SED-30003, Revision 1 (Hey, 1995).

Sufficient information was provided during the assessment to determine that software configuration management is adequately documented and implemented for software acquired for use at WIPP. Section 8.0 of WP 16-2 addresses site software configuration control. Several examples of implementation of WIPP software screening and software quality assurance planning were on file for GXQ, including Software Quality Assurance Screens/Plans written in April 2000; June 2000; December 2001; and February 2004; among other historical software control correspondence.

GXQ Software Quality Assurance

Some historical program documentation is on file for GXQ Version 3.1. However, only GXQ Version 4.0A has been in actual use at the WIPP. The bulk of SQA documentation on file applies to GXQ Version 4.0A.

Software QA Screens/Plans are filed for both Versions 3.1 and 4.0A. The most recent SQA screening (for GXQ) was completed in February 2004. The SQA forms reviewed are appropriately completed and include provision for identification of the software products to which they apply, the organizations responsible for maintaining software quality, required documentation, methods for error reporting and developing corrective actions, and post-installation configuration control.

GXQ Software Procurement

GXQ is government-sponsored software, attained from the developer. The developer provided original V&V and user documentation. The software was subsequently evaluated prior to use at the WIPP site. Several SQA screenings/plans are on file.

In addition to the SQA screening/plans on file, WP 02-RP.01, Revision 0, *WIPP Site Atmospheric Dispersion Coefficient (X/Q) Calculations,* provides indication of software testing, resulting in confidence that GXQ produces accurate and consistent results (Faulk, 2000).

In general, Sections 3.0 and 4.0 of WP 16-2 make provision for software that is purchased for or by WTS, or developed for or by WTS, or any software that is received by WTS (including freeware and shareware), to be evaluated for its application against the requirements of Title 40 *Code of Federal Regulations* (CFR) §194.22, "Quality Assurance," and WP 13-1, *WTS Quality Assurance Program Description.* That is, software is to be screened by the cognizant engineer/manager to determine if it falls under any of the categories of 40 CFR §194.22, or WTS QAPD.

GXQ Software Problem Reporting and Corrective Action

WIPP requirements for software problem reporting and corrective action are adequately documented in WP 16-2. Although provision is made for corrections and changes, per the cognizant individual, WIPP has made no changes to the GXQ program. Version 4.0A is currently in use, and has been used since 2001.

Code update information was provided to WIPP by the developer, and there have been no additional issues (Hey, 1995). Further, WP 02-RP.01, Revision 0, *WIPP Site Atmospheric Dispersion Coefficient (X/Q) Calculations,* provides indication of software testing, resulting in confidence that GXQ produces accurate and consistent results (Faulk, 2000).

No errors, problems, or failures have occurred that could be attributed to the GXQ program during its use at WIPP.

VI. Documents and References

10 CFR 835, *Occupational Radiation Protection*

40 CFR 194, *Criteria for the Certification and Re-Certification of the Waste Isolation Pilot Plant's Compliance with the 40 CFR Part 191 Disposal Regulations*, Section 22, Quality Assurance

ALGM-D-U-0796-004, *Dose Calculation algorithm for The Department of Energy Laboratory Accreditation Program*, Bicron NE (1996)

ASME NQA-2a-1990 addenda, Part 2.7, *Quality Assurance Requirements of Computer Software for Nuclear Facility Applications*

CCC-700, *MCNP4C: Monte Carlo N-Particle Transport Code System*

DOE/CBFO-94-1012, *Quality Assurance Program Document (QAPD)*

DOE/CBFO 97-2273, *WIPP Waste Information System User's Guide – WWIS Version 4.17*, 06/01/04

DOE/EH-0026, *Handbook for the Department of Energy Laboratory Accreditation Program for Personnel Dosimetry Systems*, U.S. Department of Energy (1986)

DOE/EH-0027, *Department of Energy Standard for the Performance Testing Of Personnel Dosimetry Systems*, U.S. Department of Energy (1986)

DOE/WIPP-03-3174, Revision 0, *Remote-Handled Preliminary Safety Analysis Report*

DOE/WIPP-95-2065, Revision 8, *Contact-Handled Documented Safety Analysis*

HPRS-C-U-0898-003, *Health Physics Record System (HPRS) User's Manual*, Bicron NE (1998)

MCNP4C2 *Verification and Validation, Robert Hayes,* 6/29/01

PL-24331, *DOELAP Algorithm (PL-24331) Revision History*, Bicron NE

Purchase Order 7094, *Statement of Work for Software in Purchase Requisition Change Notice Number 2*

WHC-SD-GN-SWD-30002, Revision 0, *GXQ 3.1 Users' Guide* [including code verification]

WHC-SD-GN-SWD-30002, Revision 1A, *GXQ 4.0 Program Users' Guide*

WHC-SD-GN-SWD-30003, Revision 1, *GXQ Program Verification and Validation*

WID E98-06A, *Quality Assurance Audit Report,* Westinghouse Waste Isolation Division

WP 02-RP.01, Revision 0, *WIPP Site Atmospheric Dispersion Coefficient (X/Q) Calculations*

WP 04-IM1000, Revision 0, *Issues Management Program Processing of WIPP FORMs*

WP 08-NT.01, Revision 10, *WIPP Waste Information System Program and Data Management Plan*

WP 08-NT.03, Revision 5, *Waste Stream Profile Form Review and Approval Program*

WP 08-NT.04, Revision 6, *WIPP Waste Information System Configuration Management and Software Quality Assurance Program*

WP 08-NT.05, Revision 2, *WIPP Waste Information System Software Verification and Validation Plan*

WP 08-NT.06, Revision 3, *WIPP Waste Information System Software Requirements Specification*

WP 08-NT.07, Revision 3, *WIPP Waste Information System Software Design Description*

WP 08-NT.09, Revision 0, *Security Plan for WIPP Waste Information System*

WP 13-QA3012, Revision 15, *Supplier evaluation/Qualification*

WP 13-1, Revision 24, *WTS Quality Assurance Program Description*

WP 16-2, Revision 4, *Software Screening and Action Plan*

WP 16-IT3117, Attachment 1, *Software Quality Assurance Plan for Software Application Life Cycle*

Unnumbered

Waste Isolation Pilot Plant Software Quality Assurance Assessment Plan (June 2004)

Hey, B. E. (2004) Email from B. Hey to C. Nesser, subject: GXQ Changes

Hey, B. E. (2004) Email from B. Hey to C. Nesser, subject: GXQ Versions

Hey, B. E. (1995) Memo from B. Hey to Distribution, subject: GXQ Code Update

Patton, M. W. (2004) Email from W. Patton to C. Nesser, subject: GXQ

Patton, M. W. (2004) Email from W. Patton to C. Nesser, subject: GXQ Modifications

Test Plan for Updated HPRS Algorithm, Washington TRU Solutions (2001)

WTES Software Design Description

WTES Software Requirements Specification

Appendix A. Biographical Sketch of WIPP SQA Assessment Team Members

Team Lead: Chuan-Fu Wu, Ph.D., CHP

Assessment Experience and Technical Leadership

1. Chair, Health Physics Society Laboratory Accreditation Assessment Committee (LAAC), 2002 – present.
2. Oversight Board Member, DOE Laboratory Accreditation Program (DOELAP), 2000 – present; DOELAP Assessor, 1990 – 2004.
3. Leader or Team Member, Facility Operational Readiness Review/Assessment.
4. Committee Chair, ANSI N 42.18, *American National Standard – Specification and Performance of On-Site Instrumentation for Continuously Monitoring Radioactivity in Effluent,* 2001 – present.
5. Member, U.S. Technical Advisory Group to the International Electrotechnical Commission (IEC) Technical Committee 45B, *Radiation Protection Instrumentation,* 1996 – present.

Education

- **Ph.D., Nuclear Engineering**, Massachusetts Institute of Technology (MIT), 1984 - 1987.
- **Executive MBA,** University of New Mexico, 1995 – 1997.
- **MS, Health Physics,** National Tsing-Hua University, Taiwan, 1977 – 1979.
- **BS, Nuclear Engineering,** National Tsing-Hua University, Taiwan, 1973 – 1977.

Professional Experience

- April 2000 – Present: Authorization Basis Senior Technical Advisor, DOE Carlsbad Field Office. Qualified Senior Technical Safety Manager. Responsible for overall integration of the technical programs and resources that impact the safety and operations of the Waste Isolation Pilot Plant (WIPP).
- 1998 – 2000: Technical Integration Manager, WIPP M&O Contractor. Provided technical support to research and development programs at WIPP, including international and domestic technological collaborations.
- 1995 – 1998: Environmental and Radiological Control (E&RC) Manager, WIPP. Established and managed the Radiological Control Program, the Radiochemistry Laboratory, the Environmental Monitoring Program, and the Nuclear Safety Program.
- 1990 – 1995: Dosimetry and Analytical Technology Manager, WIPP. Established the WIPP Low Level Counting Laboratory, the Volatile Organic Compound (VOC) Monitoring Program, and the Analytical Laboratory.
- 1989 – 1990: Dosimetry Program Manager, WIPP.
- 1988 – 1989: Senior Health Physicist, Oak Ridge National Laboratory.
- 1984 – 1987: Research/Teaching Assistant, MIT.
- 1981-1984: Radiation Dosimetry & Measurement Group Supervisor, Institute of Nuclear Energy Research, Taiwan.

Mary E. "Lea" Chism

Technical Assessment Experience and Capability

1. Lead Auditor (NQA-1, 1989), 1999 – present.
2. Certified Records Coordinator, 1997 – present.
3. Extensive knowledge in transuranic (TRU) waste requirements for certification/recertification of TRU waste sites for auditing purposes.

Education

- **Associates Degree, Secretarial Administration,** New Mexico State University, 1994.
- **Certificate, TRU Waste Characterization, Certification, Transportation Processes and the Associated Legislative, Regulatory Drivers,** 1997.

Professional Experience

- 1999 – Present: Quality Assurance Specialist, Carlsbad Field Office (CBFO), Carlsbad, NM. Lead Auditor (NQA-1-1989). In addition to performing the duties of previous position as an Upward Mobility Program QA Specialist, participated in and led internal and external quality assurance audits. Attended pertinent weekly TRU waste site calls and maintained notes of changes to schedule, procedures, and audit/surveillance dates. Served as the QA representative in the review of all data for inclusion in the Compliance Recertification Application (CRA). Assisted personnel of the Los Alamos National Laboratory Carlsbad Office (LANL-CO) Actinide Chemistry program in the development and implementation of laboratory operating procedures. Served as the CBFO QA point of contact for LANL. Acted as QA Manager during the QA Manager's absence. Worked with CBFO Chief Information Officer from 1999 to 2002 regarding records issues. Responsible for writing a management procedure (MP) and reviewing several other MPs in 2004.
- 1996 – 1999: Upward Mobility Program QA Specialist, Carlsbad Area Office (CAO). This program allowed OJT, as well as classroom training to become a certified auditor/lead auditor. Qualified as an auditor in 1997 and a lead auditor in 1999. Administered Corrective Action Report (CAR) database. Responsible for tracking all NCRs from TRU waste sites, and providing monthly reports to the State of New Mexico. Maintained CAO assessment schedule and providing the information to the State of New Mexico on a monthly basis. Acted as QA Manager from 1998 to 1999.
- 1993 – 1996: Worked for multiple departments within CAO providing secretarial support; lead secretary for the CAO Manager from 1995 to1996. Responsible for scheduling meetings, making travel arrangements, and tracking all incoming and outgoing correspondence. Managed numerous sensitive and unclassified records, verbally corresponding with upper management from DOE-HQ, DOE-AL, TRU waste sites, NMED, EPA, EEG, SNL, WTS and subcontractors and any other tasks deemed necessary to keep an office running smoothly.
- 1991 – 1993: Secretary for MacTec, a subcontractor to the Waste Acceptance Criteria Certification Committee (WACCC) group of CAO. Tasked with all the requirements of keeping an office running smoothly.

Richard Farrell

Technical Assessment Experience and Capability

1. DOE Carlsbad Field Office (CBFO) Team Lead for the oversight of development and implementation of the Waste Isolation Pilot Plant (WIPP) contact-handled (CH) waste disposal operations Documented Safety Analysis (DSA), 1999 – Present.
2. CBFO Lead for the development and preparation of the WIPP remote-handled (RH) waste DSA, 1999 – Present.
3. CBFO Team Member for numerous safety, conduct of operations, and compliance assessments.
4. Homestake Mining Company's Grants New Mexico Operations Team Lead for compliance assessment of uranium milling activities with respect to Nuclear Regulatory Commission (NRC) license requirements.

Education

- **BS, Chemistry**, Northern Arizona University 1975.
- **Graduate Level Analytical Chemistry Course Work,** University of New Mexico 1981.
- **Graduate Level Radioactive Waste Management Course Work,** University of New Mexico 1992.

Professional Experience

- February 2001 – Present: Safety Officer, CBFO. Responsible for the management for CBFO of the integration of industrial, mine, radiological, and nuclear safety aspects of operations of the Waste Isolation Pilot Plant.
- September 1992 – February 2001: Health Physicist, CBFO. Responsible for the oversight of radiological control elements of WIPP operations.
- April 1990 – September 1992: Senior Engineer, Westinghouse Waste Isolation Division. Responsible for interface activities with oversight and stakeholder groups and regulators regarding WIPP operations with respect to safety, radiological control, regulatory requirements, etc.
- January 1983 – April 1990: Environmental Protection Department On-Site Manager and Radiation Safety Officer (RSO), Homestake Mining Company.
- January 1980 - January 1983: RSO for Nuclear Regulatory Commission licensed activities, Homestake Mining Company.

Bill Keeley

Technical Assessment Experience and Capability

1. Author of more than 20 organization assessment tools, including the *Work Obstacle Metric*, *Transfer of Training Evaluation Model*, *Conduct of Operations Self-Assessment*, and *Leadership Development Needs Assessment*. These tools have been shared with thousands of organizations and institutions worldwide, including NASA, NRC, Dell, Intel, United Nations, Harvard University, and MIT.
2. Led more than 30 major assessments at WIPP, including the roof fall root cause analysis, two facility-wide conduct of operations assessments, and the WTS management training needs assessment.
3. Conducted a training assessment and a conduct of operations assessment at the request of the President of Westinghouse Hanford Company following a fatal accident and a significant radiological contamination event at Hanford.
4. Author of case study in a best-selling business book, which describes the assessment and development of the WIPP safety culture.
5. Assessed the quality of root cause analyses in DOE complex occurrence reports at the request of DOE-HQ.

Education

- **BA, History,** Eastern Illinois University, 1971-1974.
- **Graduate work in History and Education,** Eastern Illinois University, 1974-1975, and New Mexico State University, 1990-1991.
- **Working on MS in Organizational Behavior**, University of London (UK). 2000-present.

Professional Experience

- 2003-Present: Chief Information Officer, Washington TRU Solutions (WTS), WIPP. Responsible for communication, information technology, strategic planning, and organization development.
- 2001-2003: Communication and Strategic Planning Manager, WTS, WIPP.
- 1994-2001: Technology Transfer and Economic Development Manager, WTS, WIPP.
- 1990-1994: Human Resources Development and Total Quality Manager, WTS, WIPP.
- 1989-1990: Technical Training Manager, WTS, WIPP.
- 1985-1989: Nuclear Training Consultant, Plant Vogtle, GA and Westinghouse Nuclear Services Division, Zion, IL and Pittsburgh, PA.

Reinhard Michael Knerr

Technical Assessment Experience and Capability

1. Extensive knowledge in transuranic (TRU) waste acceptance criteria and hands-on experience in the audit and certification of TRU waste characterization programs.
2. Development and implementation of safety basis for nuclear facilities, including criticality safety analysis, Technical Safety Requirements, and Unreviewed Safety Questions.

Education

- **BS, Nuclear Engineering,** Pennsylvania State University, 1993.
- Engineer-In-Training (EIT), 1993.

Professional Experience

- August 2002 – March 2004: Corporate Project Manager, DOE Headquarters. Led the project team to develop and implement corporate level changes to the DOE Office of Environmental Management business strategies and approaches with regard to low-level, mixed low-level, and TRU wastes utilizing the principles of project management.
- May 2001 – Present: National TRU Waste Certification Team Leader, DOE Carlsbad Field Office. Directed the day-to-day activities of the federal staff responsible for managing the TRU waste characterization and certification activities. Coordinated with federal and state environmental regulators and with generator sites to resolve technical issues and ensure characterization programs remained compliant within the Waste Isolation Pilot Plant's regulatory framework.
- January 1999 – May 2001: Nuclear Criticality Safety Engineer, SAIC. Provided analytical and technical support to the DOE Y-12 Plant, DOE Mound Environmental Management Project, DOE Portsmouth Gaseous Diffusion Plant, and DOE East Tennessee Technology Park nuclear criticality safety programs. Primary responsibilities included the development and peer review of nuclear criticality safety evaluations and routine inspection of operations to ensure continued compliance with existing operational nuclear criticality safety requirements.
- August 1996 – January 1999: Senior Nuclear Criticality Safety Engineer, Bechtel Jacobs Company, LLC. Developed, modified, and peer reviewed nuclear criticality safety analyses to ensure safe operations and regulatory compliance at the DOE Portsmouth Gaseous Diffusion Plant Conducted operational reviews for compliance with site nuclear criticality safety requirements. Acted as the site technical expert for nuclear criticality safety issues, nuclear criticality safety programmatic procedures, ANSI/ANS standards, off-site packaging requirements, and the site authorization basis. Completed Unreviewed Safety Question Determinations in accordance with regulatory requirements to determine whether a proposed operational activity or a change to an existing operation is within the DOE defined authorization basis. As the Alternate Installation Facility Safety Manager,

oversaw the nuclear facility safety program, including the integration of all aspects and disciplines of safety.

- December 1993 – June 1996: Nuclear Criticality Safety Engineer, Mason & Hanger Corporation, Inc. Developed, modified, and peer reviewed nuclear criticality safety analyses and programmatic documents to assure safe operations and regulatory compliance. Completed various Unreviewed Safety Question Determinations in accordance with regulatory requirements to determine whether a proposed operational activity or a change to an existing operation is within the DOE defined authorization basis.
- May 1992 – August 1992 and January 1991 – August 1991: Nuclear Engineer Co-op, Pennsylvania Power & Light Company, Susquehanna Steam Electric Station.

Catherine E. Nesser, CQA

Technical Assessment Experience and Capability

1. Certified Quality Auditor (American Society for Quality) 2003-present
2. WIPP Lead Auditor (NQA-1-1989) 2002-present
3. Examiner, New Mexico Quality Awards Program 1999-2000
4. Examiner, DOE Energy Performance Excellence Award Program 1996, 2000

Education

- **Currently Enrolled, Masters of Business Administration,** Eastern New Mexico University, 2003-present.
- **Bachelors of Business Administration,** College of the Southwest, 1990-1992
- **Registered Radiologic Technologist,** American Registry of Radiologic Technologists, 1979-1981.
- **Associate of Arts**, New Mexico Junior College, 1979

Professional Experience

- 2002–Present: Quality Assurance Analyst. Washington TRU Solutions, Carlsbad, NM. WIPP Lead Auditor (NQA-1-1989). Participated in and lead internal quality audits and vendor evaluations; administration of WTS Qualified Suppliers List.
- 1999-2002: Administrative Specialist. Washington/Westinghouse TRU Solutions, Carlsbad, NM. Participated in Quality Assurance audits and surveillances; administration of WTS Qualified Suppliers List; administration of employee suggestion/participation program(s); coordination and delivery of quality-based training and mentoring to external organizations.
- 1992-1999: Senior Staff Assistant. Westinghouse Waste Isolation Division, Carlsbad, NM. Coordination of annual Fire Hazards Analysis update; coordination of Unreviewed Safety Question analysis, training, coordination, response, and resolution; coordination of department budget roll-up, weekly/monthly department reports; participation in national working groups within DOE complex.
- 1988-1989: Marketing Representative. Guadalupe Medical Center, Carlsbad, NM.
- 1986-1989: Radiologic Technologist. Guadalupe Medical Center, Carlsbad, NM.

John A. Stanley, MSPH, J.D.

Technical Assessment Experience and Capability

1. Lead Auditor and Technical Specialist Training, March 2001
2. CTAC Team Leader for numerous CBFO surveillances and assessments, 2001-present.
3. Technical Specialist on several CBFO audits, 2001-present.
4. Conducted numerous special assessments of segments of WIPP M&O Contractor's radiation safety, nuclear safety, and Price-Anderson programs, 2001-present.
5. CTAC Review Team Leader for review and approval of WIPP Documented Safety Analyses, 1999-present.

Education

- **J.D., Law**, University of New Mexico, 1980-1983.
- **MSPH, Radiation Physics/Radiation Biology,** University of North Carolina, 1973-1975.
- **B.S., Physics,** University of North Carolina, 1967-1971.

Professional Experience

- 2000-Present: Safety and Regulatory Compliance Specialist, S. M. Stoller Corporation, Carlsbad, NM. Provide technical and regulatory support to DOE Carlsbad Field Office (CBFO), and assist CBFO in the oversight of the Waste Isolation Pilot Plant (WIPP) Management and Operating (M&O) Contractor, in the areas of radiation protection, health and safety, industrial hygiene, nuclear safety and policy, and environmental compliance.
- 1990-2000: Senior Principal Scientist/Senior Regulatory Compliance Specialist, Commodore Advanced Sciences, Inc., Carlsbad, NM. Assisted CBFO with oversight of WIPP M&O Contractor's radiation safety and environment, safety, and health programs. Provided regulatory support to CBFO in obtaining a Hazardous Waste Facility Permit for WIPP from the New Mexico Environment Department (NMED) and in obtaining a Certification of Compliance from the Environmental Protection Agency (EPA). Project manager for preparation of various National Environmental Policy Act (NEPA) documents at the Hanford facility.
- 1985-1990: Partner in law firm of King and Stanley, Moriarty, NM. Managed the litigation-related portion of a general-practice law firm.
- 1983-1985: Associate Attorney, Martinez and Allman law firm, Denver, CO. Assisted in research, case preparation, and trial of cases alleging injury due to radiation exposure.
- 1975-1980: Staff scientist for Inhalation Toxicology Research Institute, Albuquerque, NM. Conducted basic research on the biological effects of inhaled radioactive materials. Managed the Radiation Measurement Operations Group.
- 1971 and 1973: Staff physicist for Harry Diamond Laboratories, Washington, D. C. Conducted research on the vulnerability of missile systems to radiation from detonated nuclear weapons.
- 1972-1973: Active Duty Staff Physicist for Air Force Weapons Laboratory, Kirtland AFB, Albuquerque, NM. Principal contributor to research on the vulnerability of satellite and missile systems to radiation from detonated nuclear weapons.

Dave Wiedenhoeft

Technical Assessment Experience and Capability

1. Quality Assurance Specialist for the WIPP M&O Contractor, 1999 – present. Perform software quality assurance reviews and serve as software quality assurance technical specialist in vendor audits.
2. Twenty-eight years experience in Department of Energy nuclear defense site and commercial nuclear power plant construction and operation in various quality assurance and other capacities, 1976 – present.

Education

- **BS, Computer Studies,** University of Maryland, 2003.
- **BA, Slavic Studies,** Indiana University, 1970.

Professional Experience

- March 1999 – Present: Quality Assurance Specialist, WIPP M&O Contractor. Develop and administer the quality assurance program. Develop and maintain quality assurance department procedures. Perform software quality assurance reviews.
- 1997 – 1999: Technical Writer, Rocky Flats Environmental Technology Site.
- 1996 – 1997: Technical Writer, Cooper Nuclear Station
- 1996 – 1996: Potential Issue Investigator. Evaluated potential issues, nonconformances, programmatic deficiencies, and recommended corrective actions, Perry Nuclear Power Plant.
- 1995 – 1995: Inspector, Fernald Environmental Management Project.
- 1991 – 1995: Quality Assurance Specialist, Rocky Flats Environmental Technology Site. Helped develop and maintain site quality assurance program. Served as member of Nuclear Weapons Complex Software Quality Assurance Subcommittee.
- 1990 – 1990: Work Order Planner, Perry Nuclear Power Plant.
- 1990 – 1990: Inspector, Wolf Creek Generating Station.
- 1984 – 1989: Quality Engineer/Inspector, Perry Nuclear Power Plant.
- 1981 – 1984: Inspector, Enrico Fermi Nuclear Power Plant.
- 1980 – 1981: Inspector, Perry Nuclear Power Plant.
- 1976 – 1980: Inspector, Clinton Nuclear Power Plant.

Appendix B. Objective, Criteria, and Approach for SQA Assessment

1. Software Requirements Description

Objective:

Analysis and design software functions, requirements, and their bases are defined and documented.

Criteria:

1. The functional and performance requirements for the analysis and design software are complete and detailed to perform software design.
2. The SRD is reviewed, controlled, and maintained.
3. Each requirement should be uniquely identified and defined such that it can be objectively verified and validated.

Approach:

Determine the existence of SRD documentation, either as a standalone document or embedded in another document, and ensure that it specifies, as applicable, the following:

- Functionality – the functions the software is to perform;
- Performance – the time-related issues of software operation such as speed, recovery time, and response time;
- Design constraints imposed on implementation-phase activities – any elements that will restrict design options;
- Attributes – non-time-related issues of software operation such as portability, acceptance criteria, access control, and maintainability; and
- External interfaces – interactions with people, hardware, and other software.

Determine whether the documents containing the SRD are controlled under configuration change control and document control processes. Verify that the SRD is reviewed and updated as necessary for completeness, consistency, and feasibility for developing a usable code.

Identify the standards and guidelines from applicable site/facility procedures, Federal, or industry standards that are applied to the development of the software. Determine their appropriateness and adequacy for the specific analysis and design software under assessment.

If the above requirements are not available, the perceived software requirements may be identified through available documentation and discussions with the program developer, users, and sponsor. These perceived requirements would then be used as the basis for other topical area assessment activities.

2. Software Design Description

Objective:

The SDD depicting the major components of the software design is defined and documented.

Criteria:

1. All software-related requirements are implemented in the design.
2. All design elements are traceable to the requirements.
3. The SDD is reviewed, controlled, and maintained.

Approach:

Review the appropriate documents, such as vendor specifications for analyzing and designing software, a description of the components and subcomponents of the software design, including databases and internal interfaces, etc. The design may be documented in a standalone document such as an SDD or embedded in other documents. The SDD should contain the information listed below:

- A description of the major safety components of the software design as they relate to the software requirements;
- A technical description of the software with respect to control flow, control logic, mathematical model, and data structure and integrity;
- A description of the allowable or prescribed ranges for inputs and outputs;
- A description of error handling strategy and use of interrupt protocols; and
- The design should be described in a manner suitable for translating into computer codes.

Determine whether the documents containing the software requirement description are controlled under configuration change control and document control processes. Verify that these documents are reviewed and updated as necessary for completeness, consistency, technical adequacy, and correctness.

In instances where the software design description is not available, the contractor may be able to construct a design summary on the basis of available program documentation, review of the source code (if applicable), and information from the facility staff. Care should be taken to ensure that such a design summary is consistent with the complexity and importance of the software to the safety functions.

3. Software User Documentation

Objective:

Software documentation is available to guide the user in installing, operating, managing, and maintaining the software.

Criteria:

1. The system requirements and constraints, installation procedures, and maintenance procedures such as database fine-tuning are clearly and accurately documented.
2. Any operational data system requirements and limitations are clearly and accurately documented.
3. Documentation exists to aid the users in the correct operation of the software and to provide assistance for error conditions.

4. Appropriate software design and coding documentation to assist in any future software modifications is defined and documented.

Approach:

The team will review the user's manual and related documents. These documents may exist either as a standalone document or embedded in other documents. The user documentation should contain:

- User instructions that contain an introduction, a description of the user's interaction with the software, and a description of any required training necessary to use the software;
- Input and output specifications appropriate for the function being performed;
- A description of error messages or other indications as a result of improper input or system problems and user response;
- Information for obtaining user and maintenance support;
- A description of system requirements and limitations such as operating system versions, minimum disk and memory requirements, and any known incompatibilities with other software;
- A description of any system requirements or limitations for operational data, such as file sizes;
- Recommendations for routine database maintenance and instructions for performing this maintenance; and
- Design diagrams, structure or flow charts, pseudo code, and source code listings necessary for performing future modifications of custom software.

4. Software Verification and Validation

Objective:

The software V & V process is defined and performed, and related documentation is maintained to ensure that (a) the software adequately and correctly performs all intended functions, and (b) the software does not perform any unintended function.

Criteria:

1. All analysis and design software requirements and design have been verified and validated for correct operation using testing, observation, or inspection techniques.
2. Relevant abnormal conditions have been evaluated for mitigating unintended functions through testing, observation, or inspection techniques.

Approach:

Review the software V & V documentation, either as a standalone document or embedded in another document, to determine if:

- The tasks and criteria are documented for verifying the software in each development phase and validating it at completion;
- The hardware and software configurations pertaining to the software V & V are specified; Traceability to both software requirements and design exists;
- Results of the V & V activities, including test plans, test results, and reviews are documented;

- A summary of the status of the software's completeness is documented, Changes to software are subjected to appropriate V&V;
- V & V is complete, and all unintended conditions are dispositioned before software is approved for use; and
- V & V is performed by individuals or organizations that are sufficiently independent.

5. Software Configuration Management

Objective:

The SCM process and related documentation for safety analysis and design software, including calculational software, are defined, maintained, and controlled.

Criteria:

1. All software components and products to be managed are identified.
2. For those components and products, procedures exist to manage the modification and installation of new versions.
3. Procedures for modifications to those components and products are followed.

Approach:

Review appropriate documents, such as applicable procedures related to software change control, to determine if a SCM process exists and is effective. This determination is made based on the following actions:

- Verify the existence of an SCM plan, either in standalone form or embedded in another document;
- Verify that a configuration baseline is defined and that it is being adequately controlled;
- Verify that configuration items such as operating systems, source code components, any associated runtime libraries, acquired software executables, custom-developed source code files, users' documentation, documents containing software requirements, software design, software V & V procedures, test plans, and procedures have been identified and placed under configuration control;
- Review procedures governing change management, including installation of new versions of the software components and new releases of acquired software;
- Review software change packages and work packages to ensure that (1) possible impacts of software modifications are evaluated before changes are made, (2) various software system products are examined for consistency after changes are made, and (3) software is tested according to established standards after changes have been made;
- Verify by sampling that documentation affected by software changes accurately reflects all safety- related changes that have been made to the software; and
- Interview a sample of cognizant line, engineering, and QA managers and other personnel to verify their understanding of the change control process and commitment to manage changes affecting design, safety basis, and software changes in a formal, disciplined, and auditable manner.

6. Software Quality Assurance

Objective:

SQA activities are evaluated for applicability to the analysis and design software, defmed to the appropriate level of rigor, and implemented.

Criteria:

1. SQA activities and software practices for requirements management, software design, software configuration management, procurement controls, V & V (including reviews and testing), and documentation have been evaluated and established at the appropriate level for proper applicability to the analysis and design software under assessment.
2. SQA activities have been effectively implemented.

Approach:

Determine if an appropriate SQA plan exists, either as a standalone document or embedded in another document, as well as related procedures, QA assessment reports, test reports, problem reports, corrective actions, supplier control, and training. Determine the effectiveness of the SQA program by reviewing the SQA plan. The assessment may also include interviewing managers, engineers, and software users. The SQA plan should identify:

- The software products to which it applies;
- The organizations responsible for maintaining software quality, along with their tasks and responsibilities;
- Required documentation: SRD, SDD, software user documentation, SCM plan, and software V&V plans and results;
- Standards, conventions, techniques, or methodologies that guide software development, as well as methods to ensure compliance to the same;
- Methods for error reporting and developing corrective actions; and
- Provisions for controlling software supplier activities for meeting established requirements.

7. Software Procurements

Objective:

Vendor-supplied software, either COTS software, custom-developed or modified, requires the appropriate levels of QA commensurate with the level of risk introduced by their use.

Criteria:

1. Procurement documents for acquisition of software programs identify the quality requirements appropriate for the level of risk introduced by their use.
2. Acquired software is verified to meet the identified quality requirements.

Approach:

Vendors that supply COTS and other software are evaluated to ensure that they develop software under an appropriate QA program and are capable of providing software that satisfies the specific requirements. The volume of commercial use for vendor software, especially with COTS software, should be considered in determining the adequacy of the vendor's QA program. The assessment of software procurements shall include the following:

- Determine the existence of acquired software QA requirements (These requirements may be embedded in the DOE contractor's or subcontractor's procurement requirements, SRD, SDD, or an SQA plan);
- Review the methods the site uses to verify that vendor software meets the specified QA requirements, and determine if these methods accomplish those requirements (These methods may be included in an SQA plan or software test plan); and
- Review evidence that the vendor software was evaluated for the appropriate level of quality (This evidence may be included in test results, a test summary, vendor site visit reports, or vendor QA program assessment reports).

8. Software Problem Reporting and Corrective Action

Objective:

Formal procedures for software problem reporting and corrective action for software errors and failures are established, maintained, and controlled.

Criteria:

1. Practices and procedures for reporting, tracking, and resolving problems or issues identified in both software items and software development and maintenance processes are documented and implemented.
2. Organizational responsibilities for reporting issues, approving changes, and performing corrective actions are identified and effective.

Approach:

Review documents and interview facility staff responsible for problem reporting and notification to determine if:

- A formal procedure exists for software problem reporting and corrective action development that addresses software errors, failures, and resolutions;
- Corrections and changes are executed according to established change control procedures;
- The problems that impact the software's operation are promptly reported to affected organizations;
- Corrections and changes are evaluated for impact and approved before being implemented;
- Corrections and changes are verified for correct operation and to ensure that no side effects were introduced before being implemented;
- Preventive measures and corrective actions are provided to affected organizations in a timely manner commensurate with the impact of the original defect ; and
- The organizations responsible for problem reporting and resolution are defined.

Appendix C. WIPP Waste Information System (WWIS) Lines of Inquiry

Tracking Number	Assessor	Date	Methods used: Review, Observe, Interview	Assessment questions (derived from Appendix C of the *WIPP Safety Software Quality Assurance Plan* and *CRAD-4.2.4.1*)	Yes, No, or N/A	List applicable document numbers& titles	If answer to assessment question was 'No,' List corrective action plan			Assessor notes, as applicable
							Corrective action	Due date	Lead	
4.1 Software Requirements Description										
4.1.1	BK BK, RK BK	7/12-13/04 7/14/04 8/4-5/04	R R, I R, I, O	Does SRD documentation exist, either as a standalone document or embedded in another document?	Y	08-NT.06 rev 3, "WIPP WASTE INFORMATION SYSTEM SOFTWARE REQUIREMENTS SPECIFICATION"				
4.1.2	BK BK, RK BK	7/12-13/04 7/14/04 8/4-5/04	R R, I R, I, O	Does SRD documentation specify, as applicable, the following? 4.1.2.1 Functionality 4.1.2.2 Performance 4.1.2.3 Design constraints 4.1.2.4 Attributes 4.1.2.5 External interfaces	Y	4.1.2.1: Section 3 of 08-NT.06 4.1.2.2: Section 4.2, 4.2.1, 4.2.2 of 08-NT.06 4.1.2.3: 08-NT.07 rev 3, "WIPP WASTE INFORMATION SYSTEM SOFTWARE DESIGN DESCRIPTION" 4.1.2.4: Section 4.7 of 08-NT.06 4.1.2.5: Appendix C of DOE/CBFO 97-2273, "WIPP WASTE INFORMATION SYSTEM USERS GUIDE - WWIS VERSION 4.17." WIPP TRAMPAC Evaluation Software (WTES) interfaces are in "WTES SOFTWARE DESIGN DESCRIPTION" (not yet numbered).				All of these issues are addressed in detail in WTES software requirements spec and design documentation.
4.1.3	BK BK, RK BK	7/12-13/04 7/14/04 8/4-5/04	R R, I R, I, O	Is SRD documentation controlled under configuration change control and document control processes?	Y	08-NT.06 rev 3 Quality and Manufacturing Integrated System (QMIS)				

Tracking Number	Assessor	Date	Methods used: Review, Observe, Interview	Assessment questions (derived from Appendix C of the *WIPP Safety Software Quality Assurance Plan* and *CRAD-4.2.4.1)*	Yes, No, or N/A	List applicable document numbers& titles	If answer to assessment question was "No," List corrective action plan			Assessor notes, as applicable
							Corrective action	Due date	Lead	
4.1.4	BK BK, RK BK	7/12-13/04 7/14/04 8/4-5/04	R R, I R, O, I	Is SRD documentation reviewed and updated as necessary for completeness, consistency, and feasibility for developing a usable code?	Y*	08-NT.06 rev 3 In each Engineering Change Order (ECO)				*As needed and periodic review/update.
4.1.5	BK BK, RK BK	7/12-13/04 7/14/04 8/4-5/04	R R, I R, O, I	Are the standards and guidelines from applicable site/facility procedures, Federal, or industry standards appropriate and adequate for the development of this software system?	Y	08-NT.06 rev 3				
Note: If the above requirements are not available, the perceived software requirements may be identified through available documentation and discussions with the program developer, users, and sponsor. These perceived requirements would then be used as the basis for other topical area assessment activities.										
4.2 Software Design Description										
4.2.1	BK BK, RK BK	7/12-13/04 7/14/04 8/4-5/04	R R, I R, O, I	Does SDD exist, either as a standalone document or embedded in another document?	Y	08-NT.07 rev3, "WIPP WASTE INFORMATION SYSTEM SOFTWARE DESIGN DESCRIPTION"				
4.2.2	BK BK, RK BK	7/12-13/04 7/14/04 8/4-5	R R, I	Does the SDD contain the following information? 4.2.2.1 A description of the major safety components of the software design as they relate to the software requirements	4.2.2.1: N/A 4.2.2.2: Y 4.2.2.3: Y	4.2.2.2: Examples of control logic found in DOE/CBFO 97-2273, WTES SOFTWARE REQUIREMENTS SPECIFICATION (not yet numbered), and WTES DESIGN DESCRIPTION (not yet numbered). Control flow diagrams found in 08-NT.07 and WTES Software				

Tracking Number	Assessor	Date	Methods used: Review, Observe, Interview	Assessment questions (derived from Appendix C of the *WIPP Safety Software Quality Assurance Plan* and *CRAD-4.2.4.1)*	Yes, No, or N/A	List applicable document numbers& titles	If answer to assessment question was 'No,' List corrective action plan			Assessor notes, as applicable
							Corrective action	Due date	Lead	
				4.2.2.2 A technical description of the software with respect to control flow, control logic mathematical model, and data structure and integrity 4.2.2.3 A description of the allowable or prescribed ranges for inputs and outputs 4.2.2.4 A description of error handling strategy and use of interrupt protocols 4.2.2.5 A description of the design in a manner suitable for translating into computer codes	4.2.2.4: N/A for interrupt protocols; Y for error codes and messages 4.2.2.5: Y	Requirements Document. Examples of control flow found in WTES Design Document, with class diagrams at end of document. Mathematical formulas found in WTES Software Requirements Document. Data structure and integrity found in Data dictionary in 08-NT.07 and DOE/CBFO 97-2273, and WTES Design Document appendix discussing input and output tables. 4.2.2.3: Appendix C of DOE/CBFO 97-2273 discusses expected values and ranges for data entry using Microsoft Excel Spreadsheets. WWIS data dictionary found in Appendix F of DOE/CBFO 97-2273 also discusses some allowable data inputs. Section 8.0 (E-TRAMPAC), also describes TRAMPAC edit checks, such as weight, FGE, flammable gas, etc. Also WWIS data dictionary (Appendix B) in 08-NT.07 addresses these issues. 4.2.2.4: Interrupt protocols are not valid for a database system, since WWIS and e-TRAMPAC are not process control systems. Error codes and messages are addressed in DOE/CBFO 97-2273, B.11, Table B-1. 4.2.2.5: 08-NT.07 and DOE/CBFO 97-2273				

Tracking Number	Assessor	Date	Methods used: Review, Observe, Interview	Assessment questions (derived from Appendix C of the *WIPP Safety Software Quality Assurance Plan* and *CRAD-4.2.4.1)*	Yes, No, or N/A	List applicable document numbers& titles	If answer to assessment question was "No," List corrective action plan			Assessor notes, as applicable
							Corrective action	Due date	Lead	
4.2.3	BK BK, RK BK	7/12-13/04 7/14/04 8/4-5/04	R R, I R, I, O	Is SDD controlled under configuration change control and document control processes?	Y	08-NT.07 rev 3				
4.2.4	BK BK, RK BK	7/12-13/04 7/14/04 8/4-5/04	R R, I R, I, O	Is SDD reviewed and updated as necessary for completeness, consistency, and feasibility for developing a usable code?	SDD for WTES project: Y WWIS: N*	08-NT.07 rev 3, "WIPP WASTE INFORMATION SYSTEM SOFTWARE DESIGN DESCRIPTION"	*Update the WWIS SDD	07/05	Kump	The WWIS SDD document needs updating. Each ECO that we perform for each WWIS iteration has a requirements document that discusses new requirements for the new version, but nothing is generated that addresses design issues. Work on updating the WWIS SDD will begin following the release of 5.0 (tentatively scheduled for 11/04), because significant changes are anticipated.

Note: In instances where the software the design is not available, the contractor may be able to construct a design summary on the basis of available program documentation, review of the source code (if applicable), and information from the facility staff. Care should be taken to ensure that such a design summary is consistent with the complexity and importance of the software to the safety functions.

Tracking Number	Assessor	Date	Methods used: Review, Observe, Interview	Assessment questions (derived from Appendix C of the *WIPP Safety Software Quality Assurance Plan* and *CRAD-4.2.4.1*)	Yes, No, or N/A	List applicable document numbers& titles	If answer to assessment question was "No," List corrective action plan			Assessor notes, as applicable
							Corrective action	Due date	Lead	
4.3 Software User Documentation										
4.3.1	BK BK, RK BK	7/12-13/04 7/14/04 8/4-5/04	R R, I R, I, O	Does user documentation exist, either as a standalone document or embedded in another document?	Y	DOE/CBFO 97-2273, "WIPP WASTE INFORMATION SYSTEM USERS GUIDE - WWIS VERSION 4.17"				
4.3.2	BK BK, RK BK	7/12-13/04 7/14/04 8/4-5/04	R R, I R, I, O	Does user documentation contain the following? • User instructions that contain an introduction, a description of the user's interaction with the software, and a description of any required training necessary to use the software • Input and output specifications appropriate for the function being performed • Description of error messages or other indications as a result of improper input or system problems and user response • Information for obtaining user and maintenance support • Description of system requirements and limitations such as operating system versions, minimum disk and memory requirements, and any known incompatibilities with other software • Description of any system requirements or limitations for operational data, such as file	Y	DOE/CBFO 97-2273				A basic system design diagram is provided in Figure 5-1 of DOE/CBFO 97-2273. The database structure is described in various Tables in of DOE/CBFO 97-2273. Pseudo code and source code listings necessary for performing future modifications to the software are not considered to be appropriate for inclusion in DOE/CBFO 97-2273. Flow charts are found in 08-NT.07. Pseudo code or source code listings are not found in any

Tracking Number	Assessor	Date	Methods used: Review, Observe, Interview	Assessment questions (derived from Appendix C of the *WIPP Safety Software Quality Assurance Plan* and *CRAD-4.2.4.1)*	Yes, No, or N/A	List applicable document numbers& titles	If answer to assessment question was "No," List corrective action plan			Assessor notes, as applicable
							Corrective action	Due date	Lead	
				sizes • Recommendations for routine database maintenance and instructions for performing this maintenance • Design diagrams, structure or flow charts, pseudo code, and source code listings necessary for performing future modifications of custom software						of the WWIS documents. This is really not applicable for documenting 4GL (database system applications). This is used in documenting 3GL applications (Cobol, c, Fortran, etc). There are examples of Java pseudo code in the WTES Design Document.
4.4 Software Verification and Validation										
4.4.1	BK BK, RK BK	7/12-13/04 7/14/04 8/4-5/04	R R, I R, I, O	Does V&V documentation exist, either as a standalone document or embedded in another document?	Y	08-NT.05 rev 2, "WIPP WASTE INFORMATION SYSTEM SOFTWARE VERIFICATION AND VALIDATION PLAN"				Each release has its own completed test plan under ECO.
4.4.2	BK BK, RK BK	7/12-13/04 7/14/04 8/4-5/04	R R, I R, I, O	Are the tasks and criteria documented for verifying the software in each development phase and validating it at completion?	Y	08-NT.05 rev 2				For each WWIS software revision, the tasks and criteria for peer review are developed and documented for verifying each software change prior to implementation of

Tracking Number	Assessor	Date	Methods used: Review, Observe, Interview	Assessment questions (derived from Appendix C of the *WIPP Safety Software Quality Assurance Plan* and *CRAD-4.2.4.1)*	Yes, No, or N/A	List applicable document numbers& titles	If answer to assessment question was "No," List corrective action plan			Assessor notes, as applicable
							Corrective action	Due date	Lead	
										software and hardware changes. Performance of the source code peer review conducted during the development phase of each software revision and prior to release of the software to the users. WTES software development has detailed and documented procedures for verifying and validating their software product. This is outlined in WTES Software V&V Plan.
4.4.3	BK BK, RK BK	7/12-13/04 7/14/04 8/4-5/04	R R, I R, I, O	Are the hardware and software configurations pertaining to the software V & V specified?	Y	08-NT.05 rev 2				When both hardware and software are being changed or upgraded, configurations pertaining to the software V&V are specified. When there is no change to the hardware in conjunction with a specific WWIS

Tracking Number	Assessor	Date	Methods used: Review, Observe, Interview	Assessment questions (derived from Appendix C of the *WIPP Safety Software Quality Assurance Plan* and *CRAD-4.2.4.1)*	Yes, No, or N/A	List applicable document numbers& titles	If answer to assessment question was "No," List corrective action plan			Assessor notes, as applicable
							Corrective action	Due date	Lead	
										revision, configurations to the hardware are not specified in either the peer review or the test plan. Typically, when hardware is being changed or upgraded changes to the software are not planned.
4.4.4	BK BK, RK BK	7/12-13/04 7/14/04 08/4-5/04	R R, I R, I, O	Does traceability to both software requirements and design exist?	N/A					Software requirements are developed for each code revision.
4.4.5	BK BK, RK BK	7/12-13/04 7/14/04 8/4-5/04	R R, I R, I, O	Are the results of the V & V activities, including test plans, test results, and reviews documented?	Y	08-NT.05 rev 2				Completed test plans are in ECO packages.

Tracking Number	Assessor	Date	Methods used: Review, Observe, Interview	Assessment questions (derived from Appendix C of the *WIPP Safety Software Quality Assurance Plan* and *CRAD-4.2.4.1)*	Yes, No, or N/A	List applicable document numbers& titles	If answer to assessment question was "No," List corrective action plan			Assessor notes, as applicable
							Corrective action	Due date	Lead	
4.4.6	BK	7/12-13/04	R	Is a summary of the status of the software's completeness documented?	Y	08-NT.05 rev 2				
	BK, RK	7/14/04	R, I							
	BK	08/4-5/04	R, I, O							
4.4.7	BK	7/12-13/04	R	Are changes to software subjected to appropriate V&V?	Y	08-NT.05 rev 2				
	BK, RK	7/14/04	R, I							
	BK	8/4-5/04	R, I, O							
4.4.8	BK	7/12-13/04	R	Is V & V is complete, and all unintended conditions are dispositioned before software is approved for use?	Y	08-NT.05 rev 2				
	BK, RK	7/14/04	R, I							
	BK	8/4-5/04	R, I, O							
4.4.9	BK	7/12-13/04	R	Is V & V performed by individuals or organizations that are sufficiently independent?	Y	08-NT.05 rev 2				
	BK, RK	7/14/04	R, I							
	BK	8/4-5/04	R, I, O							

Tracking Number	Assessor	Date	Methods used: Review, Observe, Interview	Assessment questions (derived from Appendix C of the *WIPP Safety Software Quality Assurance Plan* and *CRAD-4.2.4.1)*	Yes, No, or N/A	List applicable document numbers& titles	If answer to assessment question was "No," List corrective action plan			Assessor notes, as applicable
							Corrective action	Due date	Lead	
4.5 Software Configuration Management										
4.5.1	BK BK, RK BK	7/12-13/04 7/14/04 8/4-5/04	R R, I R, I, O	Does an SCM plan exist, either in standalone form or embedded in another document?	Y	08-NT.04 rev 6, "WIPP WASTE INFORMATION SYSTEM CONFIGURATION MANAGEMENT AND SOFTWARE QUALITY ASSURANCE PROGRAM"				
4.5.2	BK BK, RK BK	7/12-13/04 7/14/04 8/4-5/04	R R, I R, O, I	Is the configuration baseline defined and is it being adequately controlled?	Y	08-NT.04 rev 6				
4.5.3	BK BK, RK BK	7/12-13/04 7/14/04 8/4-504	R R, I R, I, O	Have configuration items such as operating systems, source code components, any associated runtime libraries, acquired software executables, custom-developed source code files, users' documentation, documents containing software requirements, software design, software V & V procedures, test plans, and procedures been identified and placed under configuration control?	Y	08-NT.04 rev 6				Y: data, database configuration, custom application software, and documentation.
4.5.4	BK BK, RK BK	7/12-13/04 7/14/04 8/4-5/04	R R, I R, I, O	Do procedures governing change management, including installation of new versions of the software components and new releases of acquired software exist and are they adequate?	N*		Change 08-NT.04 to include specific WWIS installation instructions.	01/05	Kump	

Tracking Number	Assessor	Date	Methods used: Review, Observe, Interview	Assessment questions (derived from Appendix C of the *WIPP Safety Software Quality Assurance Plan* and *CRAD-4.2.4.1)*	Yes, No, or N/A	List applicable document numbers& titles	If answer to assessment question was "No," List corrective action plan			Assessor notes, as applicable
							Corrective action	Due date	Lead	
4.5.5	BK BK, RK BK	7/12-13/04 7/14/04 8/4-5/04	R R, I R, I, O	Do software change packages and work packages ensure that (1) possible impacts of software modifications are evaluated before changes are made, (2) various software system products are examined for consistency after changes are made, and (3) software is tested according to established standards after changes have been made?	Y	08-NT.04 rev 6				
4.5.6	BK BK, RK BK	7/12-13/04 7/14/04 8/4-5/04	R R, I R, I, O	Does documentation affected by software changes accurately reflect all safety-related changes that have been made to the software? (verify by sampling documentation)	N/A					There are no safety-related changes to the software.
4.5.7	BK BK, RK BK	7/12-13/04 7/14/04	R R, I R, I, O	Do line, engineering, & QA managers & other personnel understand the change control process and are committed to managing changes affecting design, safety basis, & software changes in a formal, disciplined, auditable manner? (Interview a sample)	Y	08-NT.04 rev 6				
4.6 Software Quality Assurance										
4.6.1	BK BK, RK BK	7/12-13/04 7/14/04 8/4-5/04	R R, I R, I, O	Does an appropriate SQA plan exist, either as a standalone document or embedded in another document, as well as related procedures, QA assessment reports, test reports, problem reports, corrective actions, supplier control, and training?	Y	08-NT.04 rev 6, "WIPP WASTE INFORMATION SYSTEM CONFIGURATION MANAGEMENT AND SOFTWARE QUALITY ASSURANCE PROGRAM"				

Tracking Number	Assessor	Date	Methods used: Review, Observe, Interview	Assessment questions (derived from Appendix C of the *WIPP Safety Software Quality Assurance Plan* and *CRAD-4.2.4.1)*	Yes, No, or N/A	List applicable document numbers& titles	If answer to assessment question was "No," List corrective action plan			Assessor notes, as applicable
							Corrective action	Due date	Lead	
4.6.2	BK BK, RK BK	7/12-13/04 7/14/04 8/4-5/04	R R, I R, I, O	Does the SQA plan identify the following: • The software products to which it applies • The organizations responsible for maintaining software quality, along with their tasks and responsibilities • Required documentation: SRD, SDD, software user documentation, SCM plan, and software V&V plans and results • Standards, conventions, techniques, or methodologies that guide software development, as well as methods to ensure compliance to the same • Methods for error reporting and developing corrective actions • Provisions for controlling software supplier activities for meeting established requirements	Y	08-NT.04 rev 6				
4.7 Software Procurements										
Note: The volume of commercial use for vendor software, especially with Commercial Off-the Shelf Software (COTS), should be considered in determining the adequacy of the vendor's QA program										
4.7.1	BK BK, RK BK	7/12-13/04 7/14/04 8/4-5/04	R R, I R, I, O	Are vendors that supply COTS and other software evaluated to ensure that they develop software under an appropriate QA program and are capable of providing software that satisfies the specific requirements?	Y	WP 16-2, "SOFTWARE SCREENING AND ACTION PLAN" WP 13-QA3012, "SUPPLIER EVALUATION/QUALIFICATION"				

Tracking Number	Assessor	Date	Methods used: Review, Observe, Interview	Assessment questions (derived from Appendix C of the *WIPP Safety Software Quality Assurance Plan* and *CRAD-4.2.4.1)*	Yes, No, or N/A	List applicable document numbers& titles	If answer to assessment question was "No," List corrective action plan			Assessor notes, as applicable
							Corrective action	Due date	Lead	
4.7.2	BK BK, RK BK	7/12-13/04 7/14/04 8/4-5/04	R R, I R,I, O	Do acquired software QA requirements exist? (Note: These requirements may be embedded in the DOE contractor's or subcontractor's procurement requirements, SRD, SDD, or SQA plan)	Y	WP 16-2				
4.7.3	BK BK, RK BK	7/12-13/04 7/14/04 8/4-5/04	R R, I R, I, O	Do methods the site uses to verify that vender software meets the specified QA requirements, in fact, accomplish those requirements? (Note: these methods may be included in an SQA plan or software test plan)	Y	WP 16-2				
4.7.4	BK BK, RK BK	7/12-13/04 7/14/04 8/4-5/04	R R, I R, O, I	Does evidence exist that vendor software was evaluated for the appropriate level of quality (Note: This evidence may be included in test results, a test summary, vendor site visit reports, or vendor QA program assessment reports).	Y	See screening documentation generated through WP 16-2 and associated procedures and documentation from audit/assessment reports.				
4.8 Software Problem Reporting and Corrective Action										
4.8.1	BK BK, RK BK	7/12-13/04 7/14/04 8/4-5/04	R R, I R, I, O	Does a formal procedure exist for software problem reporting and corrective action development that addresses software errors, failures, and resolutions?	Y	08-NT.04 rev 6, "WIPP WASTE INFORMATION SYSTEM CONFIGURATION MANAGEMENT AND SOFTWARE QUALITY ASSURANCE PROGRAM"				

Tracking Number	Assessor	Date	Methods used: Review, Observe, Interview	Assessment questions (derived from Appendix C of the *WIPP Safety Software Quality Assurance Plan* and *CRAD-4.2.4.1)*	Yes, No, or N/A	List applicable document numbers& titles	If answer to assessment question was "No," List corrective action plan			Assessor notes, as applicable
							Corrective action	Due date	Lead	
4.8.2	BK BK, RK BK	7/12-13/04 7/14/04 8/4-5/04	R R, I R, I, O	Are corrections and changes executed according to established change control procedures?	Y	08-NT.04				
4.8.3	BK BK, RK BK	7/12-13/04 7/14/04 8/4-5/04	R R, I R, I, O	Are problems that impact the software's operation promptly reported to affected organizations?	Y	08-NT.04				
4.8.4	BK BK, RK BK	7/12-13/04 7/14/04 8/4-5/04	R R, I R, I, O	Are corrections and changes evaluated for impact and approved before being implemented?	Y	08-NT.04				
4.8.5	BK BK, RK BK	7/12-13/04 7/14/04 8/4-5/04	R R, I R, I, O	Are corrections and changes verified for correct operation and to ensure that no side effects were introduced before being implemented?	Y	08-NT.04				

Tracking Number	Assessor	Date	Methods used: Review, Observe, Interview	Assessment questions (derived from Appendix C of the *WIPP Safety Software Quality Assurance Plan* and *CRAD-4.2.4.1)*	Yes, No, or N/A	List applicable document numbers& titles	If answer to assessment question was "No," List corrective action plan			Assessor notes, as applicable
							Corrective action	Due date	Lead	
4.8.6	BK BK, RK BK	7/12-13/04 7/14/04 8/4-5/04	R R, I R, I, O	Are preventive measures and corrective actions provided to affected organizations in a timely manner commensurate with the impact of the original defect?	N/A					The WWIS team is responsible for any preventative measures and corrective actions.
4.8.7	BK BK, RK BK	7/12-13/04 7/14/04 8/4-5/04	R R, I R, I, O	Are the organizations responsible for problem reporting and resolution defined?	Y	08-NT.04				The WWIS team is responsible for evaluating problems.

Appendix D. Personnel Dosimetry Software Lines of Inquiry

Item Number	Assessor	Date	Methods used. Review, Observe, Interview	Assessment questions (derived from Appendix C of the *WIPP Safety Software Quality Assurance Plan* and *CRAD-4.2.4.1*	Yes, No, or N/A	Applicable document numbers& titles	If answer to assessment question was "No," list corrective action plan			Assessor notes, as applicable
							Corrective action	Due date	Lead	
4.1 Software Requirements Description										
4.1.1	Richard Farrell (RF), Andy Stanley (AS)	6/24/04	R , I	Does SRD documentation exist, either as a standalone document or embedded in another document?	Y	ALGM-D-U-0796-004, BICRON Dose Calculation Algorithm for the Department of Energy Laboratory Accreditation Program User's Manual, Sections 9 and 10, lists the functional and performance requirements for the WIPP external dosimetry system.				The external dosimetry software is a proprietary product developed and sold by the Bicron NE Technology Company (now Thermo-Electron). The software takes the output from the Harshaw 8800 TLD reader and uses the data to calculate a dose. Verification and validation of the software package was performed by the vendor. ALGM-D-U-0796-004 describes the current version of the software used at WIPP. The vendor is on the WIPP Qualified Supplier List. WIPP conducts annual QA reviews of all qualified suppliers. In addition, WIPP performs a thorough audit of the vendor prior to accepting a new version of the software to ensure adequate quality assurance is implemented. WIPP QA Audit E98-06A was performed for the current software version. Audit Report E98-06A indicated only one finding and that was not associated with any of these

Item Number	Assessor	Date	Methods used: Review, Observe, Interview	Assessment questions (derived from Appendix C of the *WIPP Safety Software Quality Assurance Plan* and *CRAD-4.2.4.1*	Yes, No, or N/A	Applicable document numbers& titles	If answer to assessment question was "No," list corrective action plan			Assessor notes, as applicable
							Corrective action	Due date	Lead	
										checklist items. Results of this audit are relied upon for verification of those checklist items not directly verifiable through this assessment.
4.1.2	RF	6/24/04	R, I	Does SRD documentation specify, as applicable, the following? • Functionality • Performance • Design constraints • Attributes • External interfaces	Y	ALGM-D-U-0796-004, Sections 9 and 10.				
4.1.3	RF	6/24/04	R, I	Is SRD documentation controlled under configuration change control and document control processes?	Y	ALGM-D-U-0796-004; E98-06A				The User's Manual is issued by the vendor and cannot be modified by the user.
4.1.4	RF	6/24/04	R, I	Is SRD documentation reviewed and updated as necessary for completeness, consistency, and feasibility for developing a usable code?	Y					The vendor reviews and updates the SRD when the software is revised. See Note for Item 4.1.1

Item Number	Assessor	Date	Methods used: Review, Observe, Interview	Assessment questions (derived from Appendix C of the *WIPP Safety Software Quality Assurance Plan* and *CRAD-4.2.4.1*	Yes, No, or N/A	Applicable document numbers& titles	If answer to assessment question was "No," list corrective action plan			Assessor notes, as applicable
							Corrective action	Due date	Lead	
4.1.5	RF	6/24/04	R, I	Are the standards and guidelines from applicable site/facility procedures, Federal, or industry standards appropriate and adequate for the development of this software system?	Y	DOE/EH-0026, *Handbook for the Department of Energy Laboratory Accreditation Program for Personnel Dosimetry Systems*, December 1986; DOE/EH-0027, *Department of Energy Standard for the Performance Testing of Personnel Dosimetry Systems*, December 1986				The software was developed to implement DOE Laboratory Accreditation Program (DOELAP) standards (see also Note for Item 4.1.1).
Note: If the above requirements are not available, the perceived software requirements may be identified through available documentation and discussions with the program developer, users, and sponsor. These perceived requirements would then be used as the basis for other topical area assessment activities.										
4.2 Software Design Description										
4.2.1	RF	6/24/04	R, I	Does SDD exist, either as a standalone document or embedded in another document?	Y	ALGM-D-U-0796-004, Sections 9 and 10				
4.2.2	RF	6/24/04	R, I	Does the SDD contain the following information? • A technical description of the software with respect to control flow, control logic mathematical model, and data structure and integrity • A description of the allowable or prescribed ranges for inputs and outputs • A description of error handling strategy and use of interrupt protocols • A description of the design in a manner	Y	ALGM-D-U-0796-004, Sections 7-10				

Item Number	Assessor	Date	Methods used: Review, Observe, Interview	Assessment questions (derived from Appendix C of the *WIPP Safety Software Quality Assurance Plan* and *CRAD-4.2.4.1*)	Yes, No, or N/A	Applicable document numbers& titles	If answer to assessment question was "No," list corrective action plan			Assessor notes, as applicable
							Corrective action	Due date	Lead	
				suitable for translating into computer codes						
4.2.3	RF	6/24/04	R, I	Is SDD controlled under configuration change control and document control processes?	Y	ALGM-D-U-0796-004; E98-06A				The software user's manual is issued by the vendor and cannot be changed. Vendor qualification assessment conducted by WIPP found that the vendor does have an effective document control process. See also Note for Item 4.1.1.
4.2.4	RF	6/24/04	R, I	Is SDD reviewed and updated as necessary for completeness, consistency, and feasibility for developing a usable code?	Y	Statement of Work (SOW) for Software in Purchase Requisition Change Notice # 2 of Purchase Order 70894				The Code was first developed in 1989. It was modified in July 1998 and changes to the SDD were reviewed by WIPP and documented to be in accordance with the requirements of the SOW.
Note: In instances where the software the design is not available, the contractor may be able to construct a design summary on the basis of available program documentation, review of the source code (if applicable), and information from the facility staff. Care should be taken to ensure that such a design summary is consistent with the complexity and importance of the software to the safety functions.										
4.3 Software User Documentation										
4.3.1	RF	6/24/04	R, I	Does user documentation exist, either as a standalone document or embedded in another document?	Y	ALGM-D-U-0796-004				
4.3.2	RF	6/30/04	R, I	Does user documentation contain the following? • User instructions that contain an introduction, a description of the user's interaction with the software, and a	Y	ALGM-D-U-0796-004 (see Notes for applicable sections); HPRS-C-U-0898-003, Health Physics Record system (HPRS) User's Manual				The Forward to the manual contains an introduction. Sections 2 and 3 contain a description of user interaction with the software. No training requirements are listed in the

Item Number	Assessor	Date	Methods used: Review, Observe, Interview	Assessment questions (derived from Appendix C of the *WIPP Safety Software Quality Assurance Plan* and *CRAD-4.2.4.1*	Yes, No, or N/A	Applicable document numbers& titles	If answer to assessment question was "No," list corrective action plan			Assessor notes, as applicable
							Corrective action	Due date	Lead	
				description of any required training necessary to use the software • Input and output specifications appropriate for the function being performed • Description of error messages or other indications as a result of improper input or system problems and user response • Information for obtaining user and maintenance support • Description of system requirements and limitations such as operating system versions, minimum disk and memory requirements, and any known incompatibilities with other software • Description of any system requirements or limitations for operational data, such as file sizes • Design diagrams, structure or flow charts, pseudo code, and source code listings necessary for performing future modifications of custom software						manual; however WIPP requires completion of Qualification Cards D01, *Harshaw 8800C TLD System Equipment Qualification Card,* and DS02, *Processing Center Qualification Card,* prior to running the software. Input and output specifications are contained in Sections 3 and 8. Error message descriptions are contained in Section 7. Section 2.1, *Installation,* refers questions about installation to Bicron. The manual also containes a "troubleshooting" form that states that assistance may be obtained from Bicron Customer Support. The minimum system requirements are listed in the introduction to HPRS-C-U-0898-003. The SOW states that the DOELAP external dose calculation algorithm (or software) must be capable of running the Health Physics Record system, which is described in HPRS-C-U-0898-003. Data input file requirements are provided in Sections 2.2

Item Number	Assessor	Date	Methods used: Review, Observe, Interview	Assessment questions (derived from Appendix C of the *WIPP Safety Software Quality Assurance Plan* and *CRAD-4.2.4.1*	Yes, No, or N/A	Applicable document numbers& titles	If answer to assessment question was "No," list corrective action plan			Assessor notes, as applicable
							Corrective action	Due date	Lead	
										and 8.1 of ALGM-D-U-0796-004. Section 10 provides a step-by step detail suitable for manual calculation of dose.
4.4 Software Verification and Validation										
4.4.1	RF, AS	6/30/04	R, I	Does V&V documentation exist, either as a standalone document or embedded in another document?	Y	ALGM-D-U-0796-004, Section 11; WTS Test Plan for Updated HPRS Algorithm (Test Plan)				V&V was performed on initial software and configuration changes by vendor. Validation was also performed as part of acceptance testing by WIPP in accordance with the Test Plan. The Test Plan and test results document the performance testing of the upgraded WIPP system and software.
4.4.2	RF, AS	6/30/04	R	Are the tasks and criteria documented for verifying the software in each development phase and validating it at completion?	Y	E98-06A; SOW				The vendor is on the Qualified supplier list and has been audited by WIPP to ensure adequate quality assurance / controls are in place. (See also Note for Item 4.1.1)
4.4.3	RF	6/30/04	R	Are the hardware and software configurations pertaining to the software V & V specified?	Y	E98-06A				This Item could not be verified directly. However, since it is within the scope of the WIPP Assessment reported in E98-06A and there were no negative findings reported in this area, it is inferred that the item is satisfied.

Item Number	Assessor	Date	Methods used: Review, Observe, Interview	Assessment questions (derived from Appendix C of the *WIPP Safety Software Quality Assurance Plan* and *CRAD-4.2.4.1*	Yes, No, or N/A	Applicable document numbers& titles	If answer to assessment question was "No," list corrective action plan			Assessor notes, as applicable
							Corrective action	Due date	Lead	
4.4.4	RF	6/30/04	R	Does traceability to both software requirements and design exist?	Y	E98-06A				This Item could not be verified directly. However, since it is within the scope of the WIPP Assessment reported in E98-06A and there were no negative findings reported in this area, it is inferred that the item is satisfied.
4.4.5	RF	6/30/04	R	Are the results of the V & V activities, including test plans, test results, and reviews documented?	Y	E98-06A				This Item could not be verified directly. However, since it is within the scope of the WIPP Assessment reported in E98-06A and there were no negative findings reported in this area, it is inferred that the item is satisfied.
4.4.6	RF	6/30/04	R	Is a summary of the status of the software's completeness documented?	Y	E98-06A				This Item could not be verified directly. However, since it is within the scope of the WIPP Assessment reported in E98-06A and there were no negative findings reported in this area, it is inferred that the item is satisfied.
4.4.7	RF	6/30/04	R	Are changes to software subjected to appropriate V&V?	Y	E98-06A				This Item could not be verified directly. However, since it is within the scope of the WIPP Assessment reported in E98-06A and there were no negative findings reported in this area, it is inferred that the item is satisfied.

Item Number	Assessor	Date	Methods used: Review, Observe, Interview	Assessment questions (derived from Appendix C of the *WIPP Safety Software Quality Assurance Plan* and *CRAD-4.2.4.1*	Yes, No, or *N/A*	Applicable document numbers& titles	If answer to assessment question was "No," list corrective action plan			Assessor notes, as applicable
							Corrective action	Due date	Lead	
4.4.8	RF	6/30/04	R	Is V & V is complete, and all unintended conditions are dispositioned before software is approved for use?	Y	E98-06A				This Item could not be verified directly. However, since it is within the scope of the WIPP Assessment reported in E98-06A and there were no negative findings reported in this area, it is inferred that the item is satisfied.
4.4.9	RF	7/20/04	R, I	Is V & V performed by individuals or organizations that are sufficiently independent?	Y	Test Plan				Validation and verification was performed at the WIPP site prior to implementation of the software by WIPP Dosimetry. The testing was performed using the black-box approach where dosimeters were exposed to a known amount of radiation, processed, and a dose was calculated. Using this black-box approach the program has been validated quarterly since 1989 by means of the dosimetry QA Blind Test protocol, in accordance with the DOE Laboratory Accreditation Program (DOELAP) requirements. WIPP Dosimetry has been accredited by DOELAP since 1989. This accreditation requires the software perform as designed.

Item Number	Assessor	Date	Methods used: Review, Observe, Interview	Assessment questions (derived from Appendix C of the *WIPP Safety Software Quality Assurance Plan* and *CRAD-4.2.4.1*	Yes, No, or N/A	Applicable document numbers& titles	If answer to assessment question was "No," list corrective action plan			Assessor notes, as applicable
							Corrective action	Due date	Lead	
4.5 Software Configuration Management										
4.5.1	RF	7/20/04	R, I	Does an SCM plan exist, either in standalone form or embedded in another document?	Y	E98-06A; SOW				The external dosimetry software is a commercial-off-the-shelf (COTS) product, and it is not the intent of this assessment to examine the vendor's configuration management of the code. Rather this assessment verifies that, for WIPP applications using the COTS product, WIPP effectively evaluated the vendor's configuration management process. (See also Note for Item 4.1.1).
4.5.2	RF, AS	7/20/04	R, I	Is the configuration baseline defined and is it being adequately controlled?	Y	BICRON's DOELAP Algorithm (PL-24331) Revision History (PL-24331); E98-06A				The Revision History of the software is maintained by the vendor. WIPP maintains a current copy of the Revision History. (See also Note for Item 4.1.1).
4.5.3	RF	7/20/04	R, I	Have configuration items such as operating systems, source code components, any associated runtime libraries, acquired software executables, custom-developed source code files, users' documentation, documents containing software requirements, software design, software V & V procedures, test plans, and procedures been identified and placed under configuration control?	Y	PL-24331; E98-06A				Same as comment for Item 4.5.1 above. The software vendor is responsible for configuration control, and inspection of the revision history documentation indicates that the vendor has an effective software configuration control process in place.

Item Number	Assessor	Date	Methods used: Review, Observe, Interview	Assessment questions (derived from Appendix C of the *WIPP Safety Software Quality Assurance Plan* and *CRAD-4.2.4.1*	Yes, No, or N/A	Applicable document numbers& titles	If answer to assessment question was "No," list corrective action plan			Assessor notes, as applicable
							Corrective action	Due date	Lead	
4.5.4	RF	7/20/04	R, I	Do procedures governing change management, including installation of new versions of the software components and new releases of acquired software exist and are they adequate?	Y	WIPP Procedures WP 12-3, *Dosimetry Program*, Section 3 and WP 12-OS132, *Material Requisition and Acceptance-Testing of Harshaw TLD Card and Holders*; E98-06A				The procedures state that software design changes are the responsibility of the vendor and that before any changes are implemented satisfactory demonstration of the software's ability to meet DOELAP performance testing is required. Audit E98-06A verified that change management by the vendor was adequate.
4.5.5	RF	7/20/04	R, I	Do software change packages and work packages ensure that (1) possible impacts of software modifications are evaluated before changes are made, (2) various software system products are examined for consistency after changes are made, and (3) software is tested according to established standards after changes have been made?	Y					Same as comment for Item 4.5.1 above.
4.5.6	RF	7/20/04	I	Does documentation affected by software changes accurately reflect all safety-related changes that have been made to the software? (verify by sampling documentation)	N/A					No safety-related changes to the software have been made.

Item Number	Assessor	Date	Methods used: Review, Observe, Interview	Assessment questions (derived from Appendix C of the *WIPP Safety Software Quality Assurance Plan* and CRAD-4.2.4.1	Yes, No, or N/A	Applicable document numbers& titles	If answer to assessment question was "No," list corrective action plan			Assessor notes, as applicable
							Corrective action	Due date	Lead	
4.5.7	RF	7/20/04	I	Do line, engineering, & QA managers & other personnel understand the change control process and are committed to managing changes affecting design, safety basis, & software changes in a formal, disciplined, auditable manner? (Interview a sample)	Y	Interview with M&O Contractor Dosimetry Team Leader				
4.6 Software Quality Assurance										
4.6.1	RF	7/20/04	R, I	Does an appropriate SQA plan exist, either as a standalone document or embedded in another document, as well as related procedures, QA assessment reports, test reports, problem reports, corrective actions, supplier control, and training?	Y	WP 16-IT3117, *Software Quality Assurance Plan*, Attachment 1; User's Manual Software and Documentation Feedback form (Feedback Form); E98-06A; SOW				Vendor SQA also verified in Audit E98-06A, as required by SOW. See also Note for Item 4.1.1.
4.6.2	RF	7/20/04	R, I	Does the SQA plan identify the following: • The software products to which it applies • The organizations responsible for maintaining software quality, along with their tasks and responsibilities • Required documentation: SRD, SDD, software user documentation, SCM plan, and software V&V plans and results • Standards, conventions, techniques, or methodologies that guide software development, as well as methods to ensure compliance to the same • Methods for error reporting and developing corrective actions • Provisions for controlling software supplier activities for meeting established requirements	Y	E98-06A; SOW				WP 12-3 states that the software vendor is responsible for software quality control. See also Note for Item 4.1.1.

Item Number	Assessor	Date	Methods used: Review, Observe, Interview	Assessment questions (derived from Appendix C of the *WIPP Safety Software Quality Assurance Plan* and *CRAD-4.2.4.1*)	Yes, No, or N/A	Applicable document numbers& titles	If answer to assessment question was "No," list corrective action plan			Assessor notes, as applicable
							Corrective action	Due date	Lead	
4.7 Software Procurements										
Note: The volume of commercial use for vendor software, especially with COTS software, should be considered in determining the adequacy of the vendor's QA program										
4.7.1	RF	7/20/04	R, I	Are vendors that supply COTS and other software evaluated to ensure that they develop software under an appropriate QA program and are capable of providing software that satisfies the specific requirements?	Y	E98-06A; SOW				See Note for Item 4.1.1
4.7.2	RF	7/20/04	R, I	Do acquired software QA requirements exist? (Note: These requirements may be embedded in the DOE contractor's or subcontractor's procurement requirements, SRD, SDD, or SQA plan)	Y	SOW				
4.7.3	RF	7/23/04	R, I	Do methods the site uses to verify that vendor software meets the specified QA requirements, in fact, accomplish those requirements? (Note: these methods may be included in an SQA plan or software test plan)	Y	Test Plan				The WIPP external dosimetry software test plan provided for the validation/acceptance-testing of the software after its on-site installation.
4.7.4	RF	7/23/04	R, I	Does evidence exist that vendor software was evaluated for the appropriate level of quality (Note: This evidence may be included in test results, a test summary, vendor site visit reports, or vendor QA program assessment reports).	Y	E98-06A; Test Plan				
4.8 Software Problem Reporting and Corrective Action										
4.8.1	RF	7/23/04	R, I	Does a formal procedure exist for software problem reporting and corrective action development that addresses software errors, failures, and resolutions?	Y	Feedback Form; WIPP Technology Action Request Process (TARP)				The WIPP Technology Action Request Process (TARP) is the formal feedback process used by WIPP.

Item Number	Assessor	Date	Methods used: Review, Observe, Interview	Assessment questions (derived from Appendix C of the *WIPP Safety Software Quality Assurance Plan* and *CRAD-4.2.4.1*)	Yes, No, or N/A	Applicable document numbers& titles	If answer to assessment question was "No," list corrective action plan			Assessor notes, as applicable
							Corrective action	Due date	Lead	
4.8.2	RF	7/23/04	R, I	Are corrections and changes executed according to established change control procedures?	Y	PL-24331; WP 16-IT3117, Attch. 1				
4.8.3	RF	7/23/04	I	Are problems that impact the software's operation promptly reported to affected organizations?	N/A					There are no other affected organizations.
4.8.4	RF	7/23/04	R, I	Are corrections and changes evaluated for impact and approved before being implemented?	Y	Test Plan				The Test Plan also includes the results of testing.
4.8.5	RF	7/23/04	R, I	Are corrections and changes verified for correct operation and to ensure that no side effects were introduced before being implemented?	Y	Test Plan				
4.8.6	RF	7/23/04	R, I	Are preventive measures and corrective actions provided to affected organizations in a timely manner commensurate with the impact of the original defect?	Y	WP 12-3, Section 2.2				
4.8.7	RF		R, I	Are the organizations responsible for problem reporting and resolution defined?	Y					The WIPP Dosimetry Group is the only WIPP organization that uses the software.

Appendix E. MCNP Lines of Inquiry

Tracking Number	Assessor	Date	Methods used: Review, Observe, Interview	Assessment questions (derived from Appendix C of the *WIPP Safety Software Quality Assurance Plan* and *CRAD-4.2.4.1*)	Yes, No, or N/A	List applicable document numbers& titles	If answer to assessment question was 'No,' List corrective action plan			Assessor notes, as applicable
							Corrective Action	Due date	Lead	
4.1 Software Requirements Description										
4.1.1	DW	7/13/04	R	Does SRD documentation exist, either as a standalone document or embedded in another document?	Y	CCC-700, MCNP4C: Monte Carlo N-Particle Transport Code System [MCNP Manual]				MCNP is government-sponsored software, developed at Los Alamos National Laboratory (LANL). A detailed SRD for software development was not provided with the software. However, the software requirements are described in Section 4, chapter 2 of the MCNP Manual.
4.1.2	DW	7/13/04	R I	Does SRD documentation specify, as applicable, the following? • Functionality • Performance • Design constraints • Attributes • External interfaces	Y	CCC-700				MCNP is government-sponsored software. A detailed SRD for software development was not provided with the software. However, the software requirements are described in Section 4, chapter 2 of the MCNP Manual.
4.1.3	DW	7/13/04	R	Is SRD documentation controlled under configuration change control and document control processes?	Y	CCC-700				SRD documentation is maintained by the MCNP developers. The Manual contains a Configuration Management Plan and brief discussion of document control by the developers.
4.1.4	DW	7/13/04	R	Is SRD documentation reviewed and updated as necessary for completeness, consistency, and feasibility for developing a usable code?	Y	CCC-700				SRD documentation is maintained by the MCNP developers. Review and update of the program is discussed in the MCNP Manual.
4.1.5	DW	7/13/04	R	Are the standards and guidelines from applicable site/facility procedures, Federal, or industry standards appropriate and adequate for the development of this software system?	Y	CCC-700				IEEE Software Engineering Standards Collection; ISO 9000–International Standards for Quality Management; ANSI Fortran 77 standard.
Note: If the above requirements are not available, the perceived software requirements may be identified through available documentation and discussions with the program developer, users, and sponsor. These perceived requirements would then be used as the basis for other topical area assessment activities.										

Tracking Number	Assessor	Date	Methods used: Review, Observe, Interview	Assessment questions (derived from Appendix C of the *WIPP Safety Software Quality Assurance Plan* and *CRAD-4.2.4.1*)	Yes, No, or N/A	List applicable document numbers& titles	If answer to assessment question was 'No,' List corrective action plan			Assessor notes, as applicable
							Corrective Action	Due date	Lead	
4.2 Software Design Description										
4.2.1	DW	7/13/04	R	Does SDD exist, either as a standalone document or embedded in another document?	Y	CCC-700				MCNP is government-sponsored software. A detailed SDD for software development was not provided with the software. However, the software design is described in Section 4, chapter 2 of the MCNP Manual.
4.2.2	DW	7/13/04	R I	Does the SDD contain the following information? • A description of the major safety components of the software design as they relate to the software requirements • A technical description of the software with respect to control flow, control logic mathematical model, and data structure and integrity • A description of the allowable or prescribed ranges for inputs and outputs • A description of error handling strategy and use of interrupt protocols A description of the design in a manner suitable for translating into computer codes	Y	CCC-700				MCNP is government-sponsored software. A detailed SDD for software development was not provided with the software. However, the software design is described in Section 4, chapter 2 of the MCNP Manual.
4.2.3	DW	7/13/04	R	Is SDD controlled under configuration change control and document control processes?	Y	CCC-700				SDD documentation is maintained by the MCNP developers. The Manual contains a Configuration Management Plan and brief discussion of document control by the developers.
4.2.4	DW	7/13/04	R	Is SDD reviewed and updated as necessary for completeness, consistency, and feasibility for developing a usable code?	Y	CCC-700				SDD documentation is maintained by the MCNP developers. Review and update of the program is discussed in the MCNP Manual.
Note: In instances where the software the design is not available, the contractor may be able to construct a design summary on the basis of available program documentation, review of the source code (if applicable), and information from the facility staff. Care should be taken to ensure that such a design summary is consistent with the complexity and importance of the software to the safety functions.										

Tracking Number	Assessor	Date	Methods used: Review, Observe, Interview	Assessment questions (derived from Appendix C of the *WIPP Safety Software Quality Assurance Plan* and *CRAD-4.2.4.1*)	Yes, No, or N/A	List applicable document numbers& titles	If answer to assessment question was "No," List corrective action plan			Assessor notes, as applicable
							Corrective Action	Due date	Lead	
4.3 Software User Documentation										
4.3.1	DW	7/14/04	R	Does user documentation exist, either as a standalone document or embedded in another document?	Y	CCC-700				User documentation is primarily contained in Section 4 of the MCNP Manual. Additional information is included throughout the manual.
4.3.2	DW	7/14/04	R I	Does user documentation contain the following? • User instructions that contain an introduction, a description of the user's interaction with the software, and a description of any required training necessary to use the software • Input and output specifications appropriate for the function being performed • Description of error messages or other indications as a result of improper input or system problems and user response • Information for obtaining user and maintenance support • Description of system requirements and limitations such as operating system versions, minimum disk and memory requirements, and any known incompatibilities with other software • Description of any system requirements or limitations for operational data, such as file sizes • Recommendations for routine database maintenance and instructions for performing this maintenance • Design diagrams, structure or flow charts, pseudo code, and source code listings necessary for performing future modifications of custom software	Y	CCC-700				User manual refers to the LANL/MCNP web site, which provides support. No database maintenance required by the user with this program. Not custom software.

Tracking Number	Assessor	Date	Methods used: Review, Observe, Interview	Assessment questions (derived from Appendix C of the *WIPP Safety Software Quality Assurance Plan* and *CRAD-4.2.4.1*)	Yes, No, or N/A	List applicable document numbers& titles	If answer to assessment question was 'No,' List corrective action plan			Assessor notes, as applicable
							Corrective Action	Due date	Lead	
4.4 Software Verification and Validation										
4.4.1	DW	7/14/04	R I	Does V&V documentation exist, either as a standalone document or embedded in another document?	Y	CCC-700 (SQAP); MCNP4C2 Verification and Validation, Robert Hayes, 6/29/01 [User V&V]				Section 5 of the MCNP Manual is the MCNP SQAP. Appendix A of the MCNP SQAP is the MCNP Software Verification and Validation Plan. V&V for the software development phases was performed by the MCNP developers. V&V documentation required by this section is addressed by the MCNP Software Verification and Validation Plan, and the developer certifies that the V&V was completed in accordance with the Plan. Detailed results of V&V were not provided with the Manual. The user performed and documented acceptance tests.
4.4.2	DW	7/14/04	R	Are the tasks and criteria documented for verifying the software in each development phase and validating it at completion?	Y	CCC-700 (SQAP)				V&V for the software development phases was performed by the MCNP developers.
4.4.3	DW	7/14/04	R I	Are the hardware and software configurations pertaining to the software V & V specified?	Y	CCC-700; User V&V				
4.4.4	DW	7/14/04	R	Does traceability to both software requirements and design exist?	Y	CCC-700 (SQAP)				MCNP Software Verification and Validation Plan
4.4.5	DW	7/14/04	R I	Are the results of the V & V activities, including test plans, test results, and reviews documented?	Y	CCC-700; User V&V				MCNP Software Verification and Validation Plan provides for documentation of test plans, test results, and reviews. The user performed and documented acceptance tests.

Tracking Number	Assessor	Date	Methods used: Review, Observe, Interview	Assessment questions (derived from Appendix C of the *WIPP Safety Software Quality Assurance Plan* and *CRAD-4.2.4.1*)	Yes, No, or N/A	List applicable document numbers& titles	If answer to assessment question was "No," List corrective action plan			Assessor notes, as applicable
							Corrective Action	Due date	Lead	
4.4.6	DW	7/14/04	R	Is a summary of the status of the software's completeness documented?	Y	CCC-700				The developer ceritied that the software was validated in accordance with the MCNP Software Verification and Validation Plan.
4.4.7	DW	7/14/04	R I	Are changes to software subjected to appropriate V&V?	Y	CCC-700 (SQAP); User V&V				MCNP Software Verification and Validation Plan. User performs acceptance testing.
4.4.8	DW	7/14/04	R I	Is V & V complete, and all unintended conditions are dispositioned before software is approved for use?	Y	CCC-700; User V&V				The developer ceritied that the software was validated in accordance with the MCNP Software Verification and Validation Plan. The user performed and documented acceptance tests.
4.4.9	DW	7/14/04	R	Is V & V performed by individuals or organizations that are sufficiently independent?	Y	CCC-700 (SQAP); User V&V				V&V for the software development was performed by the MCNP developers in accordance with the MCNP Software Verification and Validation Plan The user performed and documented acceptance tests.
4.5 Software Configuration Management										
4.5.1	DW	7/14/04	R I	Does an SCM plan exist, either in standalone form or embedded in another document?	Y	CCC-700 (SQAP, Appendix B, Configuration Management Plan); User V&V				MCNP developers are responsible for the program configuration management. Applicable items are maintained by the software custodian (MCNP manual, user testing documentation)
4.5.2	DW	7/14/04	R I	Is the configuration baseline defined and is it being adequately controlled?	Y	CCC-700 (SQAP, Appendix B); User V&V; WP 16-IT3117, Att. 1, Software Quality Assurance Checklist				MCNP developers are responsible for the program configuration management.. The user documentation addresses configuration management.

Tracking Number	Assessor	Date	Methods used: Review, Observe, Interview	Assessment questions (derived from Appendix C of the *WIPP Safety Software Quality Assurance Plan* and *CRAD-4.2.4.1*)	Yes, No, or N/A	List applicable document numbers& titles	If answer to assessment question was "No," List corrective action plan			Assessor notes, as applicable
							Corrective Action	Due date	Lead	
4.5.3	DW	7/14/04	R I	Have configuration items such as operating systems, source code components, any associated runtime libraries, acquired software executables, custom-developed source code files, users' documentation, documents containing software requirements, software design, software V & V procedures, test plans, and procedures been identified and placed under configuration control?	Y	CCC-700 (SQAP, Appendix B); User V&V				MCNP developers are responsible for the program configuration management. Applicable items are maintained by the software custodian (MCNP manual, user testing documentation, software executables)
4.5.4	DW	7/14/04	R	Do procedures governing change management, including installation of new versions of the software components and new releases of acquired software exist and are they adequate?	Y	CCC-700 (SQAP, Appendix B); WP 16-2				
4.5.5	DW	7/14/04	R I	Do software change packages and work packages ensure that (1) possible impacts of software modifications are evaluated before changes are made, (2) various software system products are examined for consistency after changes are made, and (3) software is tested according to established standards after changes have been made?	Y	CCC-700 (SQAP); WP 16-2				MCNP developers are responsible for the program configuration management. 16-2 requires testing of software after changes. User performs V&V of changes received from the MCNP developers.
4.5.6	DW	7/14/04	R I	Does documentation affected by software changes accurately reflect all safety-related changes that have been made to the software? (verify by sampling documentation)	Y	User V&V				Development documentation is maintained by the MCNP developers. User V&V is performed and documented for changes. No other user documentation is affected by MCNP changes.
4.5.7	DW	7/20/04	I	Do line, engineering, & QA managers & other personnel understand the change control process and are committed to managing changes affecting design, safety basis, & software changes in a formal, disciplined, auditable manner? (Interview a sample)	Y					Interviewed Robert Hayes (primary user), Anne Strait (responsible manager).

Tracking Number	Assessor	Date	Methods used: Review, Observe, Interview	Assessment questions (derived from Appendix C of the *WIPP Safety Software Quality Assurance Plan* and *CRAD-4.2.4.1*)	Yes, No, or N/A	List applicable document numbers& titles	If answer to assessment question was 'No,' List corrective action plan			Assessor notes, as applicable
							Corrective Action	Due date	Lead	
4.6 Software Quality Assurance										
4.6.1	DW	7/14/04	R	Does an appropriate SQA plan exist, either as a standalone document or embedded in another document, as well as related procedures, QA assessment reports, test reports, problem reports, corrective actions, supplier control, and training?	Y	CCC-700; WP 16-IT3117, Att. 1, Software Quality Assurance Checklist				The MCNP Manual includes a SQAP (section 5). The user documented a SQAP per the governing site procedure.
4.6.2	DW	7/14/04	R	Does the SQA plan identify the following: • The software products to which it applies • The organizations responsible for maintaining software quality, along with their tasks and responsibilities • Required documentation: SRD, SDD, software user documentation, SCM plan, and software V&V plans and results • Standards, conventions, techniques, or methodologies that guide software development, as well as methods to ensure compliance to the same • Methods for error reporting and developing corrective actions • Provisions for controlling software supplier activities for meeting established requirements	Y	CCC-700; WP 16-IT3117, Att. 1, Software Quality Assurance Checklist; WP 16-2; WP 04-IM-1000, Issues Management Program Processing of WIPP FORMs				User form Software Quality Assurance Checklist documents elements applicable to the user. User procedures WP 16-2 and 04-IM1000 provide methods for error reporting.

Tracking Number	Assessor	Date	Methods used: Review, Observe, Interview	Assessment questions (derived from Appendix C of the *WIPP Safety Software Quality Assurance Plan* and *CRAD-4.2 4.1*)	Yes, No, or N/A	List applicable document numbers& titles	If answer to assessment question was 'No,' List corrective action plan			Assessor notes, as applicable
							Corrective Action	Due date	Lead	
4.7 Software Procurements										
Note: The volume of commercial use for vendor software, especially with COTS software, should be considered in determining the adequacy of the vendor's QA program										
4.7.1	DW	7/14/04	R I	Are vendors that supply COTS and other software evaluated to ensure that they develop software under an appropriate QA program and are capable of providing software that satisfies the specific requirements?	N/A	WP 16-2				MCNP is government-sponsored software. The software was validated by the user and accepted for use in accordance with the user's SQA procedure, WP 16-2, which does not require evaluation of COTS vendors' QA programs. MCNP was developed by a DOE facility (LANL) which is required to implement applicable QA requirements. This program was assessed by LANL for the DOE safety software assessment.
4.7.2	DW	7/14/04	R I	Do acquired software QA requirements exist? (Note: These requirements may be embedded in the DOE contractor's or subcontractor's procurement requirements, SRD, SDD, or SQA plan)	Y	WP 16-2				
4.7.3	DW	7/14/04	R I	Do methods the site uses to verify that vender software meets the specified QA requirements, in fact, accomplish those requirements? (Note: these methods may be included in an SQA plan or software test plan)	Y	User V&V; WP 16-IT3117, Att. 1				
4.7.4	DW	7/14/04	R I	Does evidence exist that vendor software was evaluated for the appropriate level of quality (Note: This evidence may be included in test results, a test summary, vendor site visit reports, or vendor QA program assessment reports).	Y	User V&V				

Tracking Number	Assessor	Date	Methods used: Review, Observe, Interview	Assessment questions (derived from Appendix C of the *WIPP Safety Software Quality Assurance Plan* and *CRAD-4.2.4.1*)	Yes, No, or N/A	List applicable document numbers& titles	If answer to assessment question was "No," List corrective action plan			Assessor notes, as applicable
							Corrective Action	Due date	Lead	
4.8 Software Problem Reporting and Corrective Action										
4.8.1	DW	7/19/04	R	Does a formal procedure exist for software problem reporting and corrective action development that addresses software errors, failures, and resolutions?	Y	CCC-700 (SQAP); WP 16-2; WP 04-IM-1000				Corrective action involving software modification is the responsibilty of the developers. User procedures WP 16-2 and 04-IM1000 provide methods for error reporting.
4.8.2	DW	7/19/04	R	Are corrections and changes executed according to established change control procedures?	Y	CCC-700 (SQAP)				The developers are responsible for changes to the software. The MCNP SQAP discusses change control.
4.8.3	DW	7/19/04	R I	Are problems that impact the software's operation promptly reported to affected organizations?	Y	CCC-700 (SQAP)				The developers are responsible for reporting to the user community.
4.8.4	DW	7/19/04	R	Are corrections and changes evaluated for impact and approved before being implemented?	Y	CCC-700 (SQAP)				The developers are responsible for corrections and changes. The change process is discussed in the MCNP SQAP.
4.8.5	DW	7/19/04	R	Are corrections and changes verified for correct operation and to ensure that no side effects were introduced before being implemented?	Y	CCC-700 (SQAP)				The developers are responsible for corrections and changes. The change process is discussed in the MCNP SQAP.
4.8.6	DW	7/19/04	R	Are preventive measures and corrective actions provided to affected organizations in a timely manner commensurate with the impact of the original defect?	Y	CCC-700 (SQAP)				The developers are responsible for corrections and changes. The change process is discussed in the MCNP SQAP.
4.8.7	DW	7/19/04	R	Are the organizations responsible for problem reporting and resolution defined?	Y	CCC-700 (SQAP)				The developers are responsible for corrections and changes. The change process is discussed in the MCNP SQAP.

Appendix F. GXQ Lines of Inquiry

Tracking Number	Assessor	Date	Methods used: Review, Observe, Interview	Assessment questions (derived from Appendix C of the *WIPP Safety Software Quality Assurance Plan* and *CRAD-4.2.4.1*	Yes, No, or N/A	List applicable document numbers& titles	If answer to assessment question was "No," List corrective action plan			Assessor notes, as applicable
							Corrective Action	Due date	Lead	
4.1 Software Requirements Description										
4.1.1	CN	7/15/04	R	Does SRD documentation exist, either as a standalone document or embedded in another document?	Y	WHC-SD-GN-SWD-30003, Rev. 1, *GXQ Program Verification and Validation* DSI Memo, B. Hey to Distribution, 5/22/95 WHC-SD-GN-SWD-30002, Rev. 1A, GXQ 4.0 *Program Users' Guide*				WHC-SD-GN-SWD-30003 and WHC-SD-GN-SWD-30002 include text relative to software requirements. The DSI Memo, B. Hey to Distribution detailed changes made to the program and to relative documentation. This memo provided users with updated instructions for input; information about changes made to the program; additional warning/error messages; and changes in logic.
4.1.2	CN	7/15/04	R	Does SRD documentation specify, as applicable, the following? • Functionality • Performance • Design constraints • Attributes • External interfaces	Y	WHC-SD-GN-SWD-30003, Rev. 1 WHC-SD-GN-SWD-30002, Rev. 1A				WHC-SD-GN-SWD-30003 includes text relative to software requirements.
4.1.3	CN	7/15/04	R	Is SRD documentation controlled under configuration change control and document control processes?	Y.	WHC-CM-6-32, Rev. 0, *Safety Analysis and Regulation Work Procedures* WHC-CM-4-2, Rev. 2, *Quality Assurance Manual*				Per WHC-SD-GN-SWD-30003, GXQ documentation is controlled according to WHC-CM-4-2.

Tracking Number	Assessor	Date	Methods used: Review, Observe, Interview	Assessment questions (derived from Appendix C of the *WIPP Safety Software Quality Assurance Plan* and *CRAD-4.2.4.1*)	Yes, No, or N/A	List applicable document numbers& titles	If answer to assessment question was "No," List corrective action plan			Assessor notes, as applicable
							Corrective Action	Due date	Lead	
4.1.4	CN	7/15/04	R	Is SRD documentation reviewed and updated as necessary for completeness, consistency, and feasibility for developing a usable code?	Y	Record of Revision included with WHC-SD-GN-SWD-30003, Rev. 1 (last entry 5/10/95)				
4.1.5	CN	7/15/04	R	Are the standards and guidelines from applicable site/facility procedures, Federal, or industry standards appropriate and adequate for the development of this software system?	Y	References include: NRC Guide 1.145 WHC-CM-6-32, QI 3.2, Rev. 0, § 4.3 WHC-CM-4-2, Rev. 2 ANSI/ANS-10.4-1987				
Note: If the above requirements are not available, the perceived software requirements may be identified through available documentation and discussions with the program developer, users, and sponsor. These perceived requirements would then be used as the basis for other topical area assessment activities.										
4.2 Software Design Description										
4.2.1	CN	7/19/04	R	Does SDD exist, either as a standalone document or embedded in another document?	Y	WHC-SD-GN-SWD-30003, Rev. 1 WHC-SD-GN-SWD-30002, Rev. 1A				WHC-SD-GN-SWD-30003 and WHC-SD-GN-SWD-30002 include text relative to software design description.
4.2.2	CN	7/19/04	R	Does the SDD contain the following information? • A description of the major safety components of the software design as they relate to the software requirements • A technical description of the software with respect to control flow, control logic mathematical model, and data structure and integrity	Y	WHC-SD-GN-SWD-30003, Rev. 1 WHC-SD-GN-SWD-30002, Rev. 1A				WHC-SD-GN-SWD-30003 and WHC-SD-GN-SWD-30002 include text relative to software design description. Safety requirements are to determine dispersion coefficients for hazardous material releases. The NUREG specified how this is to be calculated, NUREG-specified

Tracking Number	Assessor	Date	Methods used: Review, Observe, Interview	Assessment questions (derived from Appendix C of the *WIPP Safety Software Quality Assurance Plan* and *CRAD-4.2.4.1*	Yes, No, or N/A	List applicable document numbers& titles	If answer to assessment question was "No," List corrective action plan			Assessor notes, as applicable
							Corrective Action	Due date	Lead	
				• A description of the allowable or prescribed ranges for inputs and outputs • A description of error handling strategy and use of interrupt protocols • A description of the design in a manner suitable for translating into computer codes						calculations are incorporated into software.
4.2.3	CN	7/19/04	R	Is SDD controlled under configuration change control and document control processes?	Y	WHC-CM-6-32, Rev. 0 WHC-CM-4-2, Rev. 2				Per WHC-SD-GN-SWD-30003, GXQ documentation is controlled according to WHC-CM-4-2.

Tracking Number	Assessor	Date	Methods used: Review, Observe, Interview	Assessment questions (derived from Appendix C of the *WIPP Safety Software Quality Assurance Plan* and *CRAD-4.2.4.1*)	Yes, No, or N/A	List applicable document numbers& titles	If answer to assessment question was "No," List corrective action plan			Assessor notes, as applicable
							Corrective Action	Due date	Lead	
4.2.4	CN	7/15/04	R, I	Is SDD reviewed and updated as necessary for completeness, consistency, and feasibility for developing a usable code?	Y	N/A				Per program developer, B. Hey, although some specialized modifications have been produced and qualified, they were not available for general distribution. The latest version of GXQ used at the WIPP is 4.0A (1995). Included in the V&V document is a record of revision (last entry 5/95). File documents refer to GXQ 4.0 and 4.0A. Per the program developer, Version 4.0A contained a small technical change which affected the way the source depletion model was used in combination with the virtual source model. The use of these models in combination would be rare and the effect small for most receptor locations. The Users' Guide and V&V documentation, however, were not impacted.
4.3 Software User Documentation										
Note: In instances where the software the design is not available, the contractor may be able to construct a design summary on the basis of available program documentation, review of the source code (if applicable), and information from the facility staff. Care should be taken to ensure that such a design summary is consistent with the complexity and importance of the software to the safety functions.										
4.3.1	CN	7/19/04	R	Does user documentation exist, either as a standalone document or embedded in another document?	Y	WHC-SD-GN-SWD-30002, Rev. 1A				
4.3.2	CN	7/19/04	R	Does user documentation contain the following? • User instructions that contain an introduction, a description of the user's interaction with the software, and a description of any required training necessary to use the software • Input and output specifications appropriate	Y	WHC-SD-GN-SWD-30002, Rev. 1A WP 16-2				GXQ is an expert program, and intended for use by individuals knowledgeable of the limits and applicability of the models implemented. Although various corrective actions for error messages are suggested, there are neither recommendations for routine database

Tracking Number	Assessor	Date	Methods used: Review, Observe, Interview	Assessment questions (derived from Appendix C of the *WIPP Safety Software Quality Assurance Plan* and *CRAD-4.2.4.1*	Yes, No, or N/A	List applicable document numbers& titles	If answer to assessment question was "No," List corrective action plan:			Assessor notes, as applicable
							Corrective Action	Due date	Lead	
				for the function being performed • Description of error messages or other indications as a result of improper input or system problems and user response • Information for obtaining user and maintenance support • Description of system requirements and limitations such as operating system versions, minimum disk and memory requirements, and any known incompatibilities with other software • Description of any system requirements or limitations for operational data, such as file sizes • Recommendations for routine database maintenance and instructions for performing this maintenance • Design diagrams, structure or flow charts, pseudo code, and source code listings necessary for performing future modifications of custom software						maintenance nor instructions for performing this maintenance included with the Users' Guide. A statement is made that maintenance is the responsibility of the user. Note: There is no database in the GXQ program. WP 16-2 charges the WIPP software custodian with the responsibility to maintain and correct the software, as necessary. WP 16-2 provides appropriate software/change control.
4.4.1	CN	7/19/04	R	Does V&V documentation exist, either as a standalone document or embedded in another document?	Y	WHC-SD-GN-SWD-30003, Rev. 1				
4.4.2	CN	7/19/04	R	Are the tasks and criteria documented for verifying the software in each development phase and validating it at completion?	Y	WHC-SD-GN-SWD-30003, Rev. 1				
4.4 Software Verification and Validation										
4.4.3	CN	7/19/04	R	Are the hardware and software configurations pertaining to the software V & V specified?	Y	WHC-SD-GN-SWD-30002, Rev. 1A				

Tracking Number	Assessor	Date	Methods used: Review, Observe, Interview	Assessment questions (derived from Appendix C of the *WIPP Safety Software Quality Assurance Plan* and *CRAD-4.2.4.1*	Yes, No, or N/A	List applicable document numbers& titles	If answer to assessment question was "No," List corrective action plan			Assessor notes, as applicable
							Corrective Action	Due date	Lead	
4.4.4	CN	7/19/04	R	Does traceability to both software requirements and design exist?	Y	WHC-SD-GN-SWD-30002, Rev. 1A				Per WHC-SD-GN-SWD-30002, Rev. 1A, *GXQ Program Users' Guide*, § 1.2, ¶ 2, GXQ is controlled by the Westinghouse Hanford Company code custodian, who is responsible for maintaining a validated version of the code/documentation and reporting any changes or errors to registered users.
4.4.5	CN	7/19/04	R	Are the results of the V & V activities, including test plans, test results, and reviews documented?	Y	WHC-SD-GN-SWD-30003, Rev. 1 WP 02-RP.01, Rev. 0, *WIPP Site Atmospheric Dispersion Coefficient (X/Q) Calculations* (3/2000)				
4.4.6	CN	7/19/04	R	I s a summary of the status of the software's completeness documented?	Y	WHC-SD-GN-SWD-30002, Rev. 1A				

Tracking Number	Assessor	Date	Methods used: Review, Observe, Interview	Assessment questions (derived from Appendix C of the *WIPP Safety Software Quality Assurance Plan* and *CRAD-4.2.4.1*	Yes, No, or N/A	List applicable document numbers& titles	If answer to assessment question was 'No,' List corrective action plan.			Assessor notes, as applicable
							Corrective Action	Due date	Lead	
4.4.7	CN	7/19/04	R	Are changes to software subjected to appropriate V&V?	Y					GXQ version in use is 4.0A, (V&V report dated 5/9/1995. V&V was performed (at Hanford facility) on 5/10/1995. [Documented Peer Review performed 3/28/95.] It is not evident that any V&V was provided for updated information distributed 5/22/95. Ample indication of WIPP QA Software screening and validation is provided in the QA Software Screening/Plans (provided for review) and WP 02-RP.01, Rev. 0.
4.4.8	CN	7/19/04	R	Is V & V complete, and all unintended conditions are dispositioned before software is approved for use? .	Y					Peer review (3/28/95) documents V&V conditions. DSI (Hanford document evidently distributed to GXQ users) dated 5/22/95 documents changes made to GXQ.
4.4.9	CN	7/19/04	R	Is V & V performed by individuals or organizations that are sufficiently independent?	Y	WHC-SD-GN-SWD-30003, Rev. 1 WP 02-RP.01				Documentation of V&V from Hanford indicates that the cognizant engineer performed the V&V, and the peer review was performed by the principal user, testing (WIPP Site) of the software was performed in 5/2000 (attachment to WP 16-IT3117, Rev. 1, Attachment 1, *Software Quality Assurance Plan (7/18/00).* The rationale used to develop and model site specific relative concentrations values (X/Q) for use in assessing doses from effluent released from the WIPP is documented in WP 02-RP.01 (3/2000).

Tracking Number	Assessor	Date	Methods used: Review, Observe, Interview	Assessment questions (derived from Appendix C of the *WIPP Safety Software Quality Assurance Plan* and *CRAD-4.2.4.1*	Yes, No, or N/A	List applicable document numbers& titles	If answer to assessment question was "No," List corrective action plan			Assessor notes, as applicable
							Corrective Action	Due date	Lead	
4.5 Software Configuration Management										
4.5.1	CN	7/20/04	R	Does an SCM plan exist, either in standalone form or embedded in another document?	Y	WHC-SD-GN-SWD-30002, Rev. 1A				SCM is addressed in WHC-SD-GN-SWD-30002, Rev. 1A
4.5.2	CN	7/20/04	R	Is the configuration baseline defined and is it being adequately controlled?	Y	WHC-SD-GN-SWD-30002, Rev. 1A				WHC-SD-GN-SWD-30002, Rev. 1A, and Software Screening Forms and Software QA Plans are on file.
4.5.3	CN	7/20/04	R	Have configuration items such as operating systems, source code components, any associated runtime libraries, acquired software executables, custom-developed source code files, users' documentation, documents containing software requirements, software design, software V & V procedures, test plans, and procedures been identified and placed under configuration control?	Y	WHC-SD-GN-SWD-30002, Rev. 1A				WHC-SD-GN-SWD-30002, Rev. 1A, and Software Screening Forms and Software QA Plans are on file.
4.5.4	CN	7/21/04	R	Do procedures governing change management, including installation of new versions of the software components and new releases of acquired software exist and are they adequate?	Y	WP 16-2				Per the cognizant engineer, during WIPP use of GXQ, no errors, problems, or failures have occurred that could be attributed to the GXQ program.

Tracking Number	Assessor	Date	Methods used: Review, Observe, Interview	Assessment questions (derived from Appendix C of the *WIPP Safety Software Quality Assurance Plan* and *CRAD-4.2.4.1*	Yes, No, or N/A	List applicable document numbers& titles	If answer to assessment question was "No," List corrective action plan			Assessor notes, as applicable
							Corrective Action	Due date	Lead	
4.5.5	CN	7/21/04	R	Do software change packages and work packages ensure that (1) possible impacts of software modifications are evaluated before changes are made, (2) various software system products are examined for consistency after changes are made, and (3) software is tested according to established standards after changes have been made?	Y					Although program documentation is on file for GXQ Version 3.1, only GXQ Version 4.0A has been in actual use at the WIPP. Software QA Screens/Plans are filed for both versions. Version 4.0A has been used consistently, without modification, by WIPP since 2001. During WIPP use of GXQ, no errors, problems, or failures have occurred that could be attributed to the GXQ program.
4.5.6	CN	7/21/04	R	Does documentation affected by software changes accurately reflect all safety-related changes that have been made to the software? (verify by sampling documentation)	N/A					Version 4.0A has been used consistently, without modification, by WIPP since 2001.

Tracking Number	Assessor	Date	Methods used: Review, Observe, Interview	Assessment questions (derived from Appendix C of the *WIPP Safety Software Quality Assurance Plan* and *CRAD-4.2.4.1*	Yes, No, or N/A	List applicable document numbers& titles	If answer to assessment question was "No," List corrective action plan			Assessor notes, as applicable
							Corrective Action	Due date	Lead	
4.5.7	CN	7/21/04	R	Do line, engineering, & QA managers & other personnel understand the change control process and are committed to managing changes affecting design, safety basis, & software changes in a formal, disciplined, auditable manner? (Interview a sample)	Y	WP 16-2 WP 12-NS.01, Rev. 5, *Changes to the WIPP Documented Safety Analyses* WP 09-CN3007, Rev. 17, *Engineering and Design Document Preparation and Change Control* WP 09-CN3034, Rev. 2, *Configuration Management Determination* WP 09-CM3035, Rev. 2, *CMS Software Configuration*				Although program documentation is on file for GXQ Version 3.1, only GXQ Version 4.0A has been in actual use at the WIPP. Software QA Screens/Plans are filed for both versions. The documents for which GXQ-derived information (CH-DSA and RH-PSAR) are extensively reviewed, internally and formally by DOE as part of the annual publication process.
4.6 Software Quality Assurance										
4.6.1	CN	7/21/04	R	Does an appropriate SQA plan exist, either as a standalone document or embedded in another document, as well as related procedures, QA assessment reports, test reports, problem reports, corrective actions, supplier control, and training?	Y	Software QA Screens/Plans for both 3.1 and 4.0 versions.				Although program documentation is on file for GXQ Version 3.1, only GXQ Version 4.0A has been in actual use at the WIPP. Software QA Screens/Plans are filed for both versions. The most recent SQA screening (for GXQ) was completed 2/9/04.
4.6.2	CN	7/21/04	R	Does the SQA plan identify the following: • The software products to which it applies • The organizations responsible for maintaining software quality, along with their tasks and responsibilities	Y	Software QA Screens/Plans for both 3.1 and 4.0 versions.				Software QA Screens/Plans are filed for both Versions 3.1 and 4.0A. The most recent SQA screening (for GXQ) was completed 2/9/04.

Tracking Number	Assessor	Date	Methods used: Review, Observe, Interview	Assessment questions (derived from Appendix C of the *WIPP Safety Software Quality Assurance Plan* and *CRAD-4.2.4.1*	Yes, No, or N/A	List applicable document numbers& titles	If answer to assessment question was "No," List corrective action plan			Assessor notes, as applicable
							Corrective Action	Due date	Lead	
				• Required documentation: SRD, SDD, - software user documentation, SCM plan, and software V&V plans and results • Standards, conventions, techniques, or methodologies that guide software development, as well as methods to ensure compliance to the same • Methods for error reporting and developing corrective actions • Provisions for controlling software supplier activities for meeting established requirements						
4.7 Software Procurements										
Note: The volume of commercial use for vendor software, especially with COTS software, should be considered in determining the adequacy of the vendor's QA program										
4.7.1	CN	7/21/04	R	Are vendors that supply COTS and other software evaluated to ensure that they develop software under an appropriate QA program and are capable of providing software that satisfies the specific requirements?	N/A					GXQ is government-sponsored software, attained from the developer. The developer provided V&V and user documentation. The software was subsequently evaluated at the WIPP site. Several SQA screenings/plans are on file. The rationale used to develop and model site specific relative concentrations values for use in assessing doses from effluent released from the WIPP is documented in WP 02-RP.01 (3/2000)

Tracking Number	Assessor	Date	Methods used: Review, Observe, Interview	Assessment questions (derived from Appendix C of the *WIPP Safety Software Quality Assurance Plan* and *CRAD-4.2.4.1*	Yes, No, or N/A	List applicable document numbers& titles	If answer to assessment question was "No," List corrective action plan			Assessor notes, as applicable
							Corrective Action	Due date	Lead	
4.7.2	CN	7/21/04	R	Do acquired software QA requirements exist? (Note: These requirements may be embedded in the DOE contractor's or subcontractor's procurement requirements, SRD, SDD, or SQA plan)	Y	WP 16-2				WP 16-2 sections 3.0 and 4.0, make provision for software that is purchased for or by WTS, or developed for or by WTS, or any software that is received by WTS (including freeware and shareware), to be evaluated for its application against the requirements of Title 40 *Code of Federal Regulations* (CFR) §194.22, "Quality Assurance," and WP 13-1, *WTS Quality Assurance Program Description*. That is, software is to be screened by the cognizant engineer/manager to determine if it falls under any of the categories of 40 CFR §194.22, or the WTS QAPD.
4.7.3	CN	7/21/04	R	Do methods the site uses to verify that vender software meets the specified QA requirements, in fact, accomplish those requirements? (Note: these methods may be included in an SQA plan or software test plan)	Y	Software QA Screens/Plans for both 3.1 and 4.0 versions.				SQA screenings/plans are prepared by the cognizant user, and reviewed by the cognizant manager, WTS QA (personnel having specific software QA expertise), and by the site information management department, NCI/ETSG. WP 02-RP.01 provides indication of software testing, resulting in confidence that GXQ produces accurate and consistent results.
4.7.4	CN	7/21/04	R	Does evidence exist that vendor software was evaluated for the appropriate level of quality (Note: This evidence may be included in test results, a test summary, vendor site visit reports, or vendor QA program assessment reports).	Y	Software QA Screens/Plans for both 3.1 and 4.0 versions.				In addition to the SQA screening/plans on file, WP 02-RP.01 provides indication of software testing, resulting in confidence that GXQ produces accurate and consistent results.

Tracking Number	Assessor	Date	Methods used: Review, Observe, Interview	Assessment questions (derived from Appendix C of the *WIPP Safety Software Quality Assurance Plan* and *CRAD-4.2.4.1*)	Yes, No, or N/A	List applicable document numbers& titles	If answer to assessment question was 'No,' List corrective action plan			Assessor notes, as applicable
							Corrective Action	Due date	Lead	
4.8 Software Problem Reporting and Corrective Action										
4.8.1	CN	7/21/04	R, I	Does a formal procedure exist for software problem reporting and corrective action development that addresses software errors, failures, and resolutions?	Y	WP 16-2				During WIPP use of GXQ, no errors, problems, or failures have occurred that could be attributed to the GXQ program.
4.8.2	CN	7/21/04	R, I	Are corrections and changes executed according to established change control procedures?	Y	WP 16-2 makes provision for corrections, changes.				WTS has made no changes to the program. Code update information was provided to WTS (formerly Westinghouse) by the developer. There have been no additional issues. Version 4.0A is currently in use, and has been used since 2001. WP 02-RP.01 provides indication of software testing, resulting in confidence that GXQ produces accurate and consistent results. During WIPP use of GXQ, no errors, problems, or failures have occurred that could be attributed to the GXQ program.
4.8.3	CN	7/21/04	R, I	Are problems that impact the software's operation promptly reported to affected organizations?	Y	WP 16-2				During WIPP use of GXQ, no errors, problems, or failures have occurred that could be attributed to the GXQ program.
4.8.4	CN	7/21/04	R, I	Are corrections and changes evaluated for impact and approved before being implemented?	Y	WP 16-2				Per the cognizant engineer, during WIPP use of GXQ, no errors, problems, or failures have occurred that could be attributed to the GXQ program.

Tracking Number	Assessor	Date	Methods used: Review, Observe, Interview	Assessment questions (derived from Appendix C of the *WIPP Safety Software Quality Assurance Plan* and *CRAD-4.2.4.1*	Yes, No, or N/A	List applicable document numbers& titles	If answer to assessment question was "No," List corrective action plan			Assessor notes, as applicable
							Corrective Action	Due date	Lead	
4.8.5	CN	7/21/04	R, I	Are corrections and changes verified for correct operation and to ensure that no side effects were introduced before being implemented?	Y	WP 16-2				During WIPP use of GXQ, no errors, problems, or failures have occurred that could be attributed to the GXQ program.
4.8.6	CN	7/21/04	R, I	Are preventive measures and corrective actions provided to affected organizations in a timely manner commensurate with the impact of the original defect?	Y	WP 16-2				During WIPP use of GXQ, no errors, problems, or failures have occurred that could be attributed to the GXQ program.
4.8.7	CN	7/21/04	R, I	Are the organizations responsible for problem reporting and resolution defined?	Y	WP 16-2				